SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 53

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
W81XWH-16-C-0002	W81XWH-15-R-0039	[ ] SEALED BID (IFB) [X] NEGOTIATED (RFP)	04 Jun 2015	0010653494-0003

7. ISSUED BY	CODE	8. ADDRESS OFFER TO (If other than Item 7)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014 TEL: FAX:	W81XWH	See Item 7 TEL: FAX:	

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder"

SOLICITATION

9. Sealed offers in original and 4 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in 820 Chandler Street, Ft Detrick until 12:00 PM (Hour) local time 27 Jul 2015 (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (Include area code) (NO COLLECT CALLS)	C. E-MAIL ADDRESS

11. TABLE OF CONTENTS

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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)				
14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE 4ANW8	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)
	FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		

15B. TELEPHONE NO (Include area code)	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
	[ ]		

AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION
CLINs 0001, 0002, 0003, 0004	$7,019,015.00	See Schedule

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified) 1	ITEM
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )		Section G

24. ADMINISTERED BY (If other than Item 7)	CODE	25. PAYMENT WILL BE MADE BY	CODE
See Item 7		DEFENSE FINANCE AND ACCOUNT NG SERVICE DFAS- NDY VP GFEBS 8899 E 56TH STREET NDIANAPOLIS N 46249-3800	HQ0490

26. NAME OF CONTRACTING OFFICER (Type or print)		28. AWARD DATE
BARRY G. SAYER TEL: (301) 619-2375 EMAIL: barry.g.sayer.civ@mail.mil	(b) (6)	19-Nov-2015

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

Section A - Solicitation/Contract Form

ADDITIONAL INFORMATION
Project Title: Support for the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)

This requirement is an R&D Service.

The NAICS code for this solicitation is 541711 (Research and Development Biotechnology).

The Government herein awards a Cost Plus Fixed Fee (CPFF) Contract

The base period of performance (POP) shall be four (4) years.

This contract is awarded in accordance with FAR 6.203, Full and Open Competition after Exclusion of Sources, Set Asides for Small Business Concerns.

Fast Track's Technical Proposal dated 28 SEP 15 and Cost Proposal dated 9 OCT 15 are incorporated by reference.

The Government Points of Contract are as follows:

Contracting Officer: Barry G. Sayer at 301-619-2375 or barry.g.sayer.civ@mail mil

Contract Specialist: Shannyn Scassero at 301-619-2640 or shannyn.scassero.civ@mail.mil

Contracting Officer's Representative: LTC (b) (6) [redacted]

FREEDOM OF INFORMATION ACT (FOIA) INQUIRIES

U.S. Army Medical Research Acquisition Activity (USAMRAA)
ATTN: MRMC-AAP-A/Nancy Gaynor
820 Chandler Street
Fort Detrick, MD 21702-5014
E-mail: nancy.gaynor.civ@mail.mil
301-619-2389

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		1	Job		$(b) (4)

TQ Development Support
CPFF
The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U. S. Army Medical Research and Materiel Command (USAMRMC)". The Contractor's proposal dated 28 SEP 15 and budget dated 9 OCT 15 are incorporated by reference. POP: 4 Years
FOB: Destination

ESTIMATED COST	$(b) (4)
FIXED FEE	$(b) (4)
TOTAL EST COST + FEE	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00

CLIN 0001 - Incremental Funding
CPFF
FOB: Destination
PURCHASE REQUEST NUMBER: 0010653494-0003

ESTIMATED COST	$0.00
FIXED FEE	$0.00
TOTAL EST COST + FEE	$0.00

ACRN AA $(b) (4)
CIN: GFEBS001065349400005

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102					$0.00
	CLIN 0001 - Incremental Funding CPFF FOB: Destination PURCHASE REQUEST NUMBER: 0010653494-0003				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AB CIN: GFEBS001065349400006				$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002 OPTION		1	Job		$(b) (4)
	Implement Clinical Study CPFF The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)", PARA 4.5. The Contractor's proposal dated 28 SEP 15 and budget dated 9 OCT 15 are incorporated by reference. FOB: Destination				
				ESTIMATED COST	$(b) (4)
				FIXED FEE	$(b) (4)
				TOTAL EST COST + FEE	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		1	Job		$475,169.00
OPTION	Execute Non-Clinical Study CPFF The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)", PARA 4.6. The Contractor's proposal dated 28 SEP 15 and budget dated 9 OCT 15 are incorporated by reference. FOB: Destination				
				ESTIMATED COST	$(b) (4)
				FIXED FEE	$(b) (4)
				TOTAL EST COST + FEE	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		4	Each	$(b) (4)	$(b) (4)
	Contractor Manpower Reporting FFP The Contractor is responsible for providing all the resources necessary to support the Contract Manpower Reporting requirement as incorporated in Section C of this RFP. Contractor may invoice for annual payment of $996 after completion of CMR requirement. POP: 4 Years FOB: Destination				
				NET AMT	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000401					$0.00
	CLIN 0004 - Incremental Funding FFP FOB: Destination PURCHASE REQUEST NUMBER: 0010653494-0003				
				NET AMT	$0.00
	ACRN AA CIN: GFEBS001065349400007				$(b) (4)

Section C - Descriptions and Specifications

STATEMENT OF OBJECTIVES

Statement of Objectives (SOO)

Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U. S. Army Medical Materiel Development Activity (USAMMDA)

C.1.0 Objective

In direct support of the US Army product development efforts to provide a prophylaxis drug for the prevention of malaria, the Government is seeking to establish a contract to complete the activities in support of a New Drug Application (NDA) for Tafenoquine (TQ), a new antimalarial drug in advance development. This effort will enable the TQ drug development program to continue with manufacturing activities as well as studies needed for the NDA. The effort will span a period of performance of four years, which will allow for drug product to be produced, additional studies to be completed, as required, and the NDA filing to be prepared and submitted by NLT 2019.

C.2.0 Background

The TQ Integrated Product Team (IPT) is in a critical phase of the drug development. The IPT has gained considerable momentum in understanding what legacy data it has for a dossier for submission to the Food and Drug Administration (FDA) regulatory authorities. The dossier will consist of thousands of pages of tabulations, charts, summaries, analyses, and numerous reports of non-clinical and clinical studies which were completed over the past 25+ years. There is at least one additional year of compilation, tabulations, charting and analysis of legacy studies necessary to complete the dossier before a Common Technical Document (CTD) is ready for submission to the FDA. To continue ongoing activities without delay, there is need to complete the remaining development activities and prepare the electronic Common Technical Document (eCTD) for submission of TQ's dossier for marketing authorization by the FDA and the Australian Therapeutics Goods Administration (TGA).

The Government and its commercial partner, 60º Pharmaceuticals, LLC, have entered into a Cooperative Research and Development Agreement (CRADA) for technology transfer of the TQ product developed by the Government. The Government's regulatory strategy is submission of a New Drug Application (NDA) to the Australian TGA, followed by a submission to the FDA. The precise timings of the drug application submissions will be by mutual consent with the overriding intent to maximize the likelihood of an FDA approval of a prophylaxis marketing authorization in the US. Submissions to Health Canada and/or European Medicines Agency (EMA) will be entirely at the discretion of the commercial partner. Ultimately, and under a separate contracting vehicle, 60° Pharmaceuticals, LLC will execute a long-term supply agreement to support the commercial marketing and distribution of TQ.

The TQ manufacturing strategy involves the Government procuring clinical product and registration batches through this proposed contract. Piramal Enterprises Limited, Healthcare Division in Mumbai, India, has developed a manufacturing process for TQ that is FDA inspected and approved for another Sponsor. Considerable time and cost savings might be gained by capitalizing on the manufacturing process established by Piramal. In addition, this specific TQ product has been qualified by the government and used in multiple clinical studies to support an NDA.

This contract will allow the Government to complete the NDA for submission to the TGA and the FDA and procure product the required non-clinical/clinical studies.

C.3.0 Period of Performance

2015 – 2019

C.4.0 Specific Tasks

C.4.1 Regulatory Support and Documentation:

C.4.1.a Prepare Common Technical Document (CTD)

The Contractor shall complete preparation activities remaining for modules 1, 2, 4 & 5 of TQ CTD required for submission to regulatory agencies. The Contractor shall provide all necessary support services to complete the remaining sections including, but not limited to, medical writing, technical support, editing and assembly of the CTD modules in paper, Non-eCTD Electronic Dossier (NeeD) or eCTD format that will comprise the NDA dossier in full compliance with the relevant regulatory requirements (DELIVERABLE No. 10/CDRL B007/QASP 7). The estimated current percent (%) completion on each Module and sub-section are:

Module 1: Administrative Information
- 1.1 Forms: 70%
- 1.2 Cover Letters: 70%
- 1.3 Administrative Information: 70%
- 1.4 References: 70%
- 1.5 Application Status: 70%
- 1.6 Meetings: 0%
- 1.7 Fast Track Request: 0%
- 1.8 Special Protocol Assessment Request: N/A
- 1.9 Pediatric Administrative Information: 0%
- 1.10 Dispute Resolution: N/A
- 1.11 Information Amendment: 70%
- 1.12 Other Correspondence: 70%
- 1.13 Annual Report: N/A
- 1.14 Labeling: 75%
- 1.15 Promotional Material: 75%
- 1.16 Risk Management Plan: 70%
- 1.17 Post-marketing Studies: 0%
- 1.18 Proprietary Names: 70%
- 1.19 Pre-EUA and EUA: 0%
- 1.20 General Investigational Plan for Initial IND: 70%

Module 2: Summaries
- 2.2 Introduction to Summary: 0%
- 2.3 Quality Overall Summary: 0%
- 2.4 Nonclinical Overview: 50%
- 2.5 Clinical Overview: 50%
- 2.6 Nonclinical Written and Tabulated Summaries: 70%
- 2.7 Clinical Summary: 70%

Module 4: Nonclinical Study Reports
- 4.2 Study Reports
- 4.2.1 Pharmacology: 70%
- 4.2.2 Pharmacokinetics: 70%
- 4.2.3 Toxicology: 70%
- 4.3 Literature References: 70%

Module 5: Clinical Study Reports
- 5.2 Tabular Listing of All Clinical Studies: 90%
- 5.3 Clinical Study Reports and Related Information: 70%
- 5.4 Literature References: 75%

C.4.1.b Prepare Electronic Common Technical Document (eCTD)

The Contractor shall provide all necessary support services to update the CTD in preparation to regulatory submission and prepare an electronic version of the dossier for submission to the regulatory agencies in full compliance with the relevant International Conference on Harmonization (ICH) CTD technical specifications and electronic submission requirements (DELIVERABLE No. 10/CDRL B007/QASP 7).

C.4.1.c Integrated CTD
The Contractor shall work closely with the TQ commercial partner (60º Pharmaceuticals, LLC, 1025 Connecticut Avenue NW, Suite 1000, Washington, D.C. 20036) and USAMMDA to write and integrate module 3 of the CTD and the Quality Summary (Module 2.3) into modules 1, 2, 4 & 5 in preparation of submission of the TQ dossier to the regulatory agencies.

C.4.1.d Organize Regulatory Pre-Submission Meeting
The Contractor shall provide writing, editing, and technical support services for the organization of a pre-NDA meeting with the regulatory agencies and preparation of meeting package (DELIVERABLE No. 15/CDRL B011/QASP 11) in full compliance with the relevant regulatory requirements. The Contractor shall also facilitate preplanning strategy sessions and rehearsals of presentations to the regulatory authorities.

C.4.1.e Manage New Drug Application Submission
The Contractor shall prepare and/or assist the TQ IPT in the production of all regulatory documents in compliance with requirements of the regulatory agencies (DELIVERABLE No. 16/CDRL B012/QASP 12). This task also includes developing and/or assisting with the development and/or review of any regulatory correspondence. The Contractor shall prepare and/or assist with communications, information requests, and preparation of meeting packages for the regulatory authorities. The content and preparation of responses shall be coordinated closely with USAMMDA's Product Manager and the commercial partner.

C.4.1 f Organize Meetings
The Contractor shall organize and host up to two CONUS and two OCONUS meetings per year with external partners and provide all the required scientific, technical, administrative, and financial support services needed for the conduct of meetings, as needed (DELIVERABLE No. 17). The number of attendees for each of the meetings is expected to be within the range of 10-20 persons. The two possible OCONUS meeting locations will be Canberra, Australia and Hyderabad, India. The CONUS meeting sites include Atlanta, GA; Philadelphia, PA; and Washington, D.C. Support services shall include travel arrangements and facilitating full participation of essential non-Government/military personnel and consultants who are needed to attend the meeting. The contractor shall generate summary reports and/or meeting minutes, as appropriate.

C.4.1.g Provide Relevant Expertise in Clinical Research and Regulatory Affairs
The Contractor shall facilitate, on an as needed basis, the identification of consultants in clinical research and regulatory affairs with broad experience in dealing with US national as well international regulatory authorities and drug licensing bodies and procure their services, either directly, or through subcontracting, to advise the TQ Product Manager and TQ IPT on the best strategies to achieve global acceptance of TQ for prophylactic indications by US and NATO forces and various relevant civilian market segments. Staff, consultants and/or contractors should have essential relevant expertise in cGLP Toxicology (est. 640 hours), Clinical Pharmacology (est. 640 hours), Ophthalmology (est. 40 hours), Malaria (est. 640 hours), Chemistry Manufacturing and Controls (CMC) (est. 640 hours) and Clinical (est. 640 hours). Staff, consultant and/or contractors shall possess the requisite education and experience in their field of expertise.

C.4.2 Prepare Market Analysis

C.4.2a Malaria Prophylaxis Market Analysis
The contractor shall provide market analysis, as needed, to assess TQ potential market size in various markets spaces such as the United States, Australia, Canada, New Zealand, and the European Union inclusive, but not limited to, Netherlands, France, United Kingdom and Germany (DELIVERABLE No. 11/CDRL B013). Market analysis shall include assessment of the corporate, public health/government and civilian travel markets. The analysis shall address current malaria chemo-prophylactic drug markets sizes, in general, and Malarone and mefloquine markets sizes, in particular. The contractor shall conduct analyses designed to assess willingness to pay using validated methodology such as the Gabor-Granger method or equivalent. The contractor shall conduct qualitative market research with a focus on the US to assess commercial trends in the use of malaria prophylactic drugs, supply chain, and access issues related to

procurement of malaria drugs. The contractor shall research demographic data for short term travelers (travelers for up to 3 weeks in endemic areas) as well as long-term travelers (travelers for longer than 3 weeks in endemic areas) in the target markets and conduct market forecasts for antimalarial drugs use amongst NATO forces.

C.4.2.b G6PD Testing Market Survey
The contractor shall research the status of G6PD testing in each market space where market analysis is undertaken and each provider/distribution channel with a view to provide input into the risk management plans and pharmacovigilance standard operating procedures for each country.

C.4.3 Procure API and Produce Registration Batches of Drug Product:

C.4.3.a The Contractor shall procure cGMP TQ Active Pharmaceutical Ingredients (API) in bulk quantity needed for formulation development. The manufacturing batches should include pilot scale (if necessary) up to and including full commercial scale production lots.

C.4.3.b The Contractor shall procure cGMP TQ Active Pharmaceutical Ingredients (API) in bulk to prepare three batches of cGMP drug product suitable for registration in target markets including the USA. Fill finish activities of the material produced should be in a tablet or capsule formulation with final packaging ready for patient administration. The Contractor shall provide copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product (DELIVERABLE No. 8/CDRL B008/ QASP 2).

C.4.3.c The Contractor shall set up a stability testing program and provide stability reports (SRs) (DELIVERABLE No. 9/CDRL B009) within five (5) business days of receipt. The stability program should conform to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines for Quality, Q1A-Q1F.

C.4.3.d As stated in 2.0 Background, PARA 2, Piramal Enterprises Limited, Healthcare Division in Mumbai, India, has extensive knowledge and expertise in producing bulk lots of TQ. The current minimum batch size for TQ is 25 kgs and the minimum number of batches needed is 3 (total amount 75 kgs). The TQ must be produced under cGMP as it is intended for clinical use in humans.

C.4.4 Implement Bioequivalence Study
A Bioequivalence Study is needed to compare product produced by Piramal or another manufacture to the product that was used in previous clinical studies. The study will show there is no meaningful difference between the two tafenoquine products in terms of the drug's safety and the way in which the drug works in the body.

The contractor shall be responsible for executing a study either directly or through subcontractors in full compliance with the relevant regulatory requirements. The protocol shall be formulated to address any and all concerns of regulatory agencies after consultation with the relevant authorities in such agencies. The protocol shall include all relevant study- associate documents such as Case Report Forms (CRFs), Informed Consent (IC), Statistical Analysis Plan (SAP), study-specific SOPs, etc.

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the protocol in full compliance with local regulatory regulations and the applicable GCP/ICH regulatory requirements.

The Contractor shall submit a final Study Report (DELIVERABLE No. 12 /CDRL B006/QASP 8).

C.4.5 Implement Clinical Study - Option CLIN 0002 (Est. POP 1 Year)
The contractor shall be responsible for executing a study either directly or through subcontractors in full compliance with the relevant regulatory requirements. The protocol shall be formulated to address any and all concerns of regulatory agencies after consultation with the relevant authorities in such agencies. The protocol shall include all relevant study- associate documents such as Case Report Forms (CRFs), Informed Consent (IC), Statistical Analysis Plan (SAP), study-specific SOPs, etc.

A 30 healthy volunteer subject malaria challenge clinical study will be performed with an anticipated period of performance of three months to nine months. Study drug will be administered as a loading dose, one dose per day for 3 days followed by weekly dosing for 3 weeks. Subjects will be followed with daily smears for 20 days and once weekly through day 60 and as needed for fever post mosquito's exposure. The contractor shall be responsible for all resources at the study sites required for subject screenings and follow-ups. The contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the clinical protocol in full compliance with local regulatory regulations and the applicable GCP/ICH regulatory requirements.

Provide quality assurance services and generate QA reports to ensure timely execution of clinical protocols in full compliance with local regulatory regulations and the applicable GCP/ICH regulatory requirements.

The Contractor shall submit a final Clinical Study Report (DELIVERABLE No. 13/CDRL B005/QASP 9) .

C.4.6 Execute Non-clinical Study - Option CLIN 0003 (Est. POP 9 Months)

C.4.6.a The Contractor shall provide all support services needed to initiate and complete a 28-day toxicology study required by the regulatory authorities.

The Contractor shall provide support to the Product Manager and the TQ IPT in developing the protocol and related documents (Ex: SOPs, etc.) consistent with and in full compliance with the relevant national and international (GLP) regulatory requirements.

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the non-clinical protocol in full compliance with local regulatory regulations and the applicable GLP regulatory requirements.

C.4.6.b The Contractor shall provide all support services needed to initiate an appropriate non-clinical test to evaluate a drug-related N-nitroso metabolite. This metabolite was negative in both a non-GLP and GLP Ames test. The contractor will be provided samples of TQ to be used in the study.

The Contractor shall provide support to the Government Product Manager and the TQ IPT in developing the protocol and related documents (Ex: SOPs, etc.) consistent with and in full compliance with the relevant national and international (GLP) regulatory requirements.

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the non-clinical protocol in full compliance with local regulatory regulations and the applicable GLP regulatory requirements.

The Contractor shall submit a final Non-Clinical Study Report (DELIVERABLE No. 14/CDRL B010/ QASP 10).

C.4.7 Provide Data Management:
On as needed basis, the Contractor shall:

C.4.7.a Provide data management services and/or data management systems, in full compliance with cGCP, ICH/FDA regulations and 21 CFR Part 11. Data management services may include, but are not limited to, Statistical Analysis Plan (SAP) and case report forms development; modification, installation, and/or qualification of data management systems; data capture, data cleansing, queries, and query resolution; database locking and reporting; formulation, as needed, and maintenance of Standard Operating Procedures (SOPs); work instructions and job descriptions related to operation of the data management; creation and operation of individual data entry systems and transfer of data by sites; responding to site queries; and filing CRFs.

C.4.7.b Provide .pdf-formatted files of primary (final) records, CRFs of each participant, study data files on DVDs or HDs and SAS-formatted data files, as needed.

C.4.7.c Perform data entry and CRF filing audits and coordinate coding of Adverse Events (AEs) using MedDRA.

C.4.7.d Provide statistical support services including (but not limited to) the development of SAPs, implement and/or purchase of statistical software, perform statistical analysis, and generate reports in full compliance with the relevant ICH/GCP regulatory requirement for inclusion in regulatory submissions.

C.4.7.e Provide database closure and archiving.

C.5.0 Prepare Project Management Approach

The Contractor shall provide a Project Management Approach. The management approach shall describe the management, processes, integration of the various aspects of the Government SOO and RFP so that the associated risks may be assessed and ability to demonstrate flexible and creative solutions to the management on this effort. Identify significant milestones, decision points, functional oversights and processes that will be used to evaluate program status and progress. Present mechanisms for interactions/communications between the Contractor and the Government. Describe the approach to managing and interfacing with key subcontractors, to include how they will assure subcontractors meet cost, schedule, and performance requirements. The Contractor's Project Management Approach shall describe teaming arrangements including a description of the teaming partner(s) and their core competencies, geographical reach of capabilities, and biographical sketches/CVs of key personnel.

C.5.1 Performance Work Statement (PWS)

The Contractor shall submit a PWS as part of the RFP submission. The PWS will provide the details as to how the contractor intends to accomplish the objectives of the Government SOO and RFP (DELIVERABLE No. 3/QASP 3). The proposed PWS, when accepted by the Government, will be incorporated into and become a material part of the contract at time of award. For that reason, this section shall be a standalone document. Any revisions will require the concurrence of both the Government and Contractor and issued in accordance with a modification to the contract.

C.5.2 Contract Work Breakdown Structure (CWBS)

The Contractor shall submit a CWBS as part of the RFP submission. The Offeror shall submit a CWBS and CWBS Dictionary, using the MIL-STD-881C (http://www.acq.osd.mil/evm/resources/policies-standards.shtml), fulfilling the requirement stated in the Government's SOO (DELIVERABLE No. 4/CDRL B001/QASP 4). The minimum CWBS expected is Level 4; however, the Offeror shall extend CWBS elements as needed to obtain the depth and breadth of detail required to define the contract scope and to accurately describe the proposed effort. The CWBS shall correlate with the PWS and Contract Line Item Numbers (CLINs). This document will be revised by the Contractor, as necessary during the contract period of performance.

C.5.3 Integrated Master Schedule (IMS)

The Contractor shall develop and maintain an Integrated Master Schedule (IMS) (DELIVERABLE No. 5/CDRL B002/QASP 5). The IMS shall contain the planned events and milestones, accomplishments and activities from contract award to the completion of contract. The IMS shall be updated as required by the COR, but not less than annually to show task progress, percent completion, and schedule slippage. Additionally, Contractor shall provide an IMS for all module and sub-section activities outlined in section 4.1a for the NDA Dossier.

C.5.4 Quality Management Plan (QMP)

The Contractor shall develop and maintain a QMP (DELIVERABLE No. 6/CDRL B004/QASP 6). The QMP provides a description of the Contractor's management steps to ensure that all activities of the project are managed in a sound, reasonable way to achieve the Government's objectives and that all deliverables produced are acceptable prior to delivery to the Government. The QMP also describes/assigns the roles and responsibilities of the Government, the Contractor, and any subcontractors.The QMP provides appropriate mechanisms and access for the Government or its designee to audit the Contractor and/or its Subcontractors for regulatory compliance and quality assurance purposes. The Contractor's QMP shall describe in detail the following:

C.5.4.a Quality standards in facilities, equipment, methods, practices, records, controls, and documentation
C.5.4.b Comprehensive GMP, GLP, and GCP compliant systems
C.5.4.c Comprehensive and adequately staffed Quality Assurance Unit
C.5.4.d Established quality agreements with teaming partners
C.5.4.e Approach to technology transfers of processes
C.5.4 f Approach to providing flexibility
C.5.4.g Ability to provide creative and timely responses to the management of the contract and subcontracts.

C.5.5 Kick-off Meeting
The Contractor shall schedule and conduct a kick-off meeting in coordination with the Government within 30 business days after contract award (DELIVERABLE No. 1). The Contractor shall meet with the Government to present an overview of their approach and establish schedules, procedures, and points of contact necessary to conduct the tasks outlined herein. This meeting shall not exceed two hours in length. The Contractor shall be responsible for drafting and finalizing meeting minutes and distributing the finalized minutes to all in attendance.

C.5.6 Recurring Status Meetings
The Contractor shall plan and conduct regular, routine meetings with a quarterly frequency, no later than one (1) week after the end of each contract year quarter,with the Government to review progress and status of activities under this task order (DELIVERABLE No. 2). Each review shall provide insight into expenditures, staffing, progress, risks. The Contractor shall provide project briefings addressing cost/price, schedule, performance, and status of each key element of this task order, noting any problems or risks and alternative and recommended solutions. The Contractor shall be responsible for drafting and finalizing meeting minutes and distributing the finalized minutes to all in attendance.

C.5.7 Quarterly Progress Report (QPR)
The Contractor shall submit a QPR outlining the expenditures, billings, progress, status, and any problems or issues encountered in the performance of this task using format provided by the Government and Contractor (Deliverable No. 7/CDRL B003/QASP 1). The QPR shall include labor hours expended by labor category and CLIN for each task and sub-task. The Contractor shall require all sub-contractors to provide input to the QPR where there are significant tasks related to the prime contract. Significant tasks shall be identified by the Contractor in the initial proposal.

C.6.0 Quality Assurance Surveillance Plan Matrix (QASP Matrix)

ITEM	Indicator	Standard	Acceptable Quality Level	Monitoring Method	Incentive
1. QPR SOO 5.7 CDRL B003 DELIVERABLE 7	Received no later than the 15th of of the month after each contract year quarter	Report of financials, status of tasks, and problems/issues including any subcontractor input	No more than 5 business days late with no less than 95% accuracy for any report in one quarter	100% review	Past performance rating

2. Finished product in final packaging and copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product SOO 4.3.b CDRL B008 DELIVERABLE 8	Contractor shall procure cGMP material NLT 17 months after contract award and provide copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product	Full compliance with cGMP standards	Full compliance with cGMP standards and delivery NLT 17 months after contract award	100% review	Past performance rating
3. PWS SOO 5.1 DELIVERABLE 3	Received at RFP closing and as required	Shall provide details as to how the contractor will accomplish the objectives of the Government SOO and RFP	Comprehensive, current and accurate throughout contract POP	100% review	Past performance rating
4. CWBS SOO 5.2 CDRL B001 DELIVERABLE 4	Received at RFP closing and within 14 business days of COR request for an update or as required	Contractor shall develop and maintain a CWBS. The CWBS elements shall be extended to define the complete contract scope and shall be to a depth and breadth necessary to accurately describe the proposed effort, to a minimum of Level 4	CWBS defines entire contract scope and extends to at least Level 4	100% review	Past performance rating
5. IMS SOO 5.3 CDRL B002 DELIVERABLE 5	Received at RFP closing and as required, but not less than annually	Contractor shall develop and maintain an IMS by logically networking detailed program activities.	Comprehensive, current and accurate IMS depicting logical network of program activities	100% review	Past performance rating

6. QMP SOO 5.4 CDRL B004 DELIVERABLE 6	Received at RFP closing and as required, but not less than annually	Contractor shall develop a comprehensive QMP to ensure that the project is managed properly and in conformance to all Government requirements. Contractor shall review and update plan as needed, at a minimum annually	Comprehensive QMP that ensures project is managed in a sound, reasonable way to achieve the Government's objectives and that all deliverables produced are acceptable prior to delivery to the Government	100% review	Past performance rating
7. Final CTD & eCTD SOO 4.1.a and 4.1.b CDRL B007 DELIVERABLE 10	Deliver modules 1, 2, 3, 4 & 5 in paper and electronic format within 30 days of government comments	Full compliance with relevant submission requirements	Not more than 5% failure to comply with requirements per module	Progress status meetings	Past performance rating
8. Final Bioequivalence Study Report SOO 4.4 CDRL B006 DELIVERABLE 12	NLT 8 months after Study Initiation	Report ready for submission to the regulatory agency	Minimal revision (less than 3 business day effort) may be required.	100% review	Past Performance rating
9.Final Clinical Study Report SOO 4.5 CDRL B005 DELIVERABLE 13	NLT 1 year after issuance of CLIN 0002	Report ready for submission to the regulatory agency	Minimal revision (less than 3 business day effort) may be required	100% review	Past performance rating
10. Final Non-Clinical Study Report SOO 4.6 CDRL B010 DELIVERABLE 14	NLT 9 months after issuance of CLIN 0003	Report ready for submission to the regulatory agency	Minimal revision (less than 3 business day effort) may be required	100% review	Past performance rating
11. Pre-submission Package SOO 4.1.d CDRL B011 DELIVERABLE 15	NLT the expiration of contract year 3	Package submitted to regulatory agency on planned schedule	Minimal revision (less than 3 business day effort) may be required	100% review	Past Performance rating
12. NDA Submission Package SOO 4.1.e CDRL B012 DELIVERABLE 16	NLT 6 months prior to contract POP expiration	Package submitted to regulatory agency on planned scheduled	Minimal revision (less than 3 business day effort) may be required	100% review	Past Performance rating

C.7.0 Security and Training Requirements
The work under the contract will not require issuance of a computer access card (CAC) or access to the government network.

C.7.1 Contractor Access to USAMMDA Network/DoD Systems:
Not Applicable

C.7.2 Antiterrorism (AT)/Operations Security (OPSEC) Requirements:

AT Level I Training. All Contractor employees, including sub-Contractor employees, requiring access to Army installations, facilities, or controlled access areas shall complete AT Level I awareness training within 15 calendar days after contract start date or effective date of incorporation of this requirement into the contract, whichever applies. The Contractor shall submit certificates of completion for each affected Contractor employee and sub-Contractor employee to the COR (or to the contracting Officer, if a COR is not assigned) within 30 calendar days after completion of training by all employees and sub-Contractor personnel. AT Level I awareness training is available at https://atlevel1.dtic.mil/at.

Access and General Protection/Security Policy and Procedures. The Contractor and all associated sub-Contractors' employees shall comply with applicable installation, facility, and area commander installation and facility access and local security policies and procedures (provided by the government representative). The Contractor shall also provide all information required for background checks to meet installation access requirements to be accomplished by the installation Provost Marshal Office, Director of Emergency Services, or Security Office. The Contractor shall comply with all personal identity verification requirements as directed by DoD, HQDA, and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in Contractor security matters or processes.

C.8.0 CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES) (APR 2011) (USAMRAA)

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including sub-contractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address: https://cmra.army mil. **T**he required information includes: (l) Contract Number; (2) Delivery Order Number (If applicable); (3) Task Order Number (If applicable); (4) Requiring Activity Unit Identification Code (UIC); (5) Command; (6) Contractor Contact Information; (7) Federal Service Code (FSC); (8) Direct Labor Hours; (9) Direct Labor Dollars; and, (10) Location. In the event the Contracting Officer's Representative (COR)/Contracting Officer's Technical Representative (COTR) has not entered their data requirements first, the contractor must also enter the COR/COTR required data with the exception of fund cite, obligations, and disbursement data. The **CMRA help desk can be reach at 703-695-5103 or 703-695-5058 for any technical questions. The help desk can also be contacted via email: contractormanpower@hqda.army mil.** As part of its quote or offer, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. The reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	Government
000102	N/A	N/A	N/A	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
000401	N/A	N/A	N/A	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-1	Contractor Inspection Requirements	APR 1984
52.246-5	Inspection Of Services Cost-Reimbursement	APR 1984
52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001
52.246-8 Alt I	Inspection Of Research And Development-Cost Reimbursement (May 2001) - Alternate I	APR 1984
52.246-9	Inspection Of Research And Development (Short Form)	APR 1984

Section F - Deliveries or Performance

DELIVERABLES LIST

No.	Deliverable	Contract or SOO Reference	Distribution To:	Initial Due Date	Subsequent Submissions
1	Kickoff meeting	5.5	COR and PM	NLT 30 days of contract award	Meeting Minutes due NLT 10 business days after meeting
2	Recurring Status Meetings	5.6	COR and PM	NLT one week after the end of each contract year quarter	Meeting Minutes due NLT 10 business days after meeting
3	PWS QASP 3	5.1	Contracting Officer (Initially) COR & PM (Subsequent)	RFP Closing Date	As required
4	CWBS CDRL B001 QASP 4	5.2	Contracting Officer (Initially) COR & PM (Subsequent)	RFP Closing Date	Within 14 business days of COR request for an update or as required
5	IMS CDRL B002 QASP 5	5.3	Contracting Officer (Initially) COR & PM (Subsequent)	RFP Closing Date	As required, but not less than annually
6	QMP CDRL B004 QASP 6	5.4	Contracting Officer (Initially) COR & PM (Subsequent)	RFP Closing Date	As required, but not less than annually
7	QPR CDRL B003 QASP 1	5.7	COR and PM	NLT the 15th day of the month after the initial 3 months of contract award	Due NLT the 15th day of the month after each contract year quarter
8	Provide finished product in final packaging and copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product CDRL B008 QASP 2	4.3.b	COR and PM	NLT 17 months after contract award	NA
9	SRs CDRL B004	4.3.c	COR and PM	NLT 5 business days after receipt of initial report	NLT 5 business days after receipt of subsequent reports

10	Final CTD and eCTD CDRL B007 QASP 7	4.1a and 4.1.b	COR and PM	NLT the expiration of contract year 3	NLT 30 calendar days after COR comments
11	Market Analysis Final Report CDRL B013	4.2	COR and PM	NLT 6 months after contract award.	N/A
12	Bioequivalence Study Final Report CDRL B006 QASP 8	4.4	COR and PM	NLT 8 months after Study Initiation	NLT 3 business days after receipt of COR comments
13	Clinical Study Final Report (Option) QASP 9 CDRL B005	4.5	COR and PM	NLT 1 year after issuance of CLIN 0002	NLT 3 business days after receipt of COR comments
14	Non-clinical Study Final Report (Option) QASP 10 CDRL B010	4.6	COR and PM	NLT 9 months after issuance of CLIN 0003	NLT 3 business days after receipt of COR comments
15	Pre-submission Package QASP 11 CDRL B011	4.1.d	COR and PM	NLT the expiration of the contract year 3	NLT 3 business days after receipt of COR comments
16	NDA Submission Package QASP 12 CDRL B012	4.1.e	COR and PM	NLT 6 months prior to the contract POP expiration	NLT 3 business days after receipt of COR comments
17	Organize Meetings (up to 2 CONUS and 2 OCONUS per year)	4.1 f	COR and PM	NLT 3 months after COR request for a meeting and provision of details to include location and attendee list	Summary Reports and/or Meeting Minutes due NLT 30 business days after meeting
18	Contractor Manpower Reporting (CMR)	C.8.0	COR	NLT 31 OCT 16	Annually NLT 31 OCT

DELIVERY INFORMATION

CLIN DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC

0001	POP 23-NOV-2015 TO 22-NOV-2019	N/A	USA MED MATERIEL DEV ACTIVITY CDR, USAMMDA 1430 VETERANS DRIVE FORT DETRICK MD 21702-9232 (b) (6) FOB: Destination	W806YH
000101	N/A	N/A	N/A	N/A
000102	N/A	N/A	N/A	N/A
0002	POP 23-NOV-2015 TO 22-NOV-2019	N/A	USA MED MATERIEL DEV ACTIVITY COMMANDER USAMMDA 1430 VETERANS DRIVE FORT DETRICK MD 21702-9232 (b) (6) FOB: Destination	W806YH
0003	POP 23-NOV-2015 TO 22-NOV-2019	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W806YH
0004	POP 23-NOV-2015 TO 22-NOV-2019	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W806YH
000401	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

CONTRACT LABOR RATES

Prime Contractor Labor Rates and Personnel

1) The Contractor shall utilize the negotiated unburdened hourly rates contained in the contract award as documented below. These rates are the ceiling hourly rates to be invoiced to the Government and are based on the negotiated annual salarys, which have been escalated 2.5% annually in Years 2 through 4. Fringe benefits, Overhead and G&A rates shall be in accordance with the applicable DHHS Negotiated Agreement documenting Fast Track Drugs & Biologics LLC Final/Provisional/Ceiling Rates.

Contract Year 1 (16 NOV 15 – 15 NOV 16).

Labor Category	Hourly Rate
Clinical Affairs Mgr	$(b)
Medical Affairs	$(b)
Safety Reviewer	$(b)
Project Admin	$(b)
Medical Writer I	$(b)
Quality Assurance Mgr	$(b)
Clinical Proj Mgr	$(b)
Sr Clinical Data Mgr	$(b)
Clinical Res Assistant	$(b)
Clinical Monitor	$(b)
Senior Biostat.	$(b)
Statistician II	$(b)
Statistician I	$(b)
Admin Assistant	$(b)

Contract Year 2 (POP: 16 NOV 16 – 15 NOV 17)

Labor Category	Hourly Rate
Clinical Affairs Mgr	$(b)
Medical Affairs	$(b)
Safety Reviewer	$(b)
Project Admin	$(b)
Medical Writer I	$(b)
Quality Assurance Mgr	$(b)
Clinical Proj Mgr	$(b)
Sr Clinical Data Mgr	$(b)
Clinical Res Assistant	$(b)
Clinical Monitor	$(b)
Senior Biostat	$(b)
Statistician II	$(b)

Statistician I	$(b)
Admin Assistant	$(b)

Contract Year 3 (POP: 16 NOV 17 – 15 NOV 18)

Labor Category	**Hourly Rate**
Clinical Affairs Mgr	$(b)
Medical Affairs	$(b) (4)
Safety Reviewer	$(b)
Project Admin	$(b)
Medical Writer I	$(b)
Quality Assurance Mgr	$(b)
Clinical Proj Mgr	$(b)
Sr Clinical Data Mgr	$(b)
Clinical Res Assistant	$(b)
Clinical Monitor	$(b)
Senior Biostat	$(b)
Statistician II	$(b)
Statistician I	$(b)
Admin Assistant	$(b)

Contract Year 4 (POP: 16 NOV 18 – 15 NOV 19)

Labor Category	**Hourly Rate**
Clinical Affairs Mgr	$(b)
Medical Affairs	$(b) (4)
Safety Reviewer	$(b)
Project Admin	$(b)
Medical Writer I	$(b)
Quality Assurance Mgr	$(b)
Clinical Proj Mgr	$(b)
Sr Clinical Data Mgr	$(b)
Clinical Res Assistant	$(b)
Clinical Monitor	$(b)
Senior Biostat	$(b)
Statistician II	$(b)
Statistician I	$(b)
Admin Assistant	$(b)

2) As the Contractor proposed specific individuals for the labor positions listed above, the Contractor agrees that, during the contract performance period, personnel substitution shall be reported promptly to the Contracting Officer. The Contractor's reporting shall include the name and qualifications, and any other information required by the

Contracting Officer, for the personnel substitution. This information shall also be provided in Contractor's Quarterly Progress Reports. Contractor agrees that all proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting Officer or his authorized representative reserves the right to evaluate the qualifications provided by the Contractor for compliance with the position requirements of equal to or higher qualifications and promptly notify the Contractor of his or her review and acceptance or disapproval of substituted and/or replaced personnel.

ACCOUNTING AND APPROPRIATION DATA

AA: 0212015201620400000664643255 R.0001626.7 6100.9000021001
COST CODE: A74FG
AMOUNT: $(b) (4)
CIN GFEBS001065349400005: $(b) (4)
CIN GFEBS001065349400007: $(b) (4)

AB: 0212016201720400000664643255 R.0001626.9 6100.9000021001
COST CODE: A74FG
AMOUNT: $(b) (4)
CIN GFEBS001065349400006: $(b) (4)

CLAUSES INCORPORATED BY REFERENCE

252.204-0002 Line Item Specific: Sequential ACRN Order SEP 2009

CLAUSES INCORPORATED BY FULL TEXT

52.004-4002 Contractor Performance Assessment Reporting System (CPARS) (USAMRAA) (September 2009)

The Contractor Performance Assessment Reporting System (CPARS) has been adopted electronically to capture assessment data and manage the evaluation process. CPARS is used to assess a contractor's performance and provide a record, both positive and negative, on a given contract during a specific period of time. The CPARS Automated Information System (AIS) collection tool and other CPARS information can be accessed at https://www.cpars.csd.disa.mil. CPARS collects contractor performance information and passes it to the Federal Past Performance Information Retrieval System (PPIRS) where it can be retrieved by Federal Government Agencies including the DoD Services. The CPARS process is designed with a series of checks and balances to facilitate the objective and consistent evaluation of contractor performance. Both government and contractor program management perspectives are captured on the CPAR form and together make a complete CPAR. The Contractor shall assign and provide to the Contracting Officer's Representative (COR), within 10 calendar days after award, the name, title, email address and phone number of the designated Contractor Representative (CR) within their firm who

will be responsible for CPAR information and reviewing the Government's proposed assessment for the period of performance. A User ID and Password for the CPARS will be provided to the designated CR for this purpose of accessing the CPARS. The CR has the authority to: Receive the Government evaluation; Review/comment/return the evaluation to the Government within 30 calendar days after the Government's evaluation is completed; Request a meeting to discuss the CPAR. This meeting must be requested, in writing, no later than seven calendar days from the receipt of the CPAR and must be held during the contractor's 30-day review period. The CR must either concur or nonconcur to each CPAR.

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(a) Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall--

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and

(2) Be registered to use WAWF at https://wawf.eb mil/ following the step-by-step procedures for self-registration available at this Web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Contractor shall use the following document type(s).

COST VOUCHER

(2) Inspection/acceptance location. The Contractor shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

W806YH

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W81XWH
Admin DoDAAC	W81XWH
Inspect By DoDAAC	W806YH
Ship To Code	W806YH
Ship From Code	NA
Mark For Code	NA
Service Approver (DoDAAC)	HAA211
Service Acceptor (DoDAAC)	W806YH
Accept at Other DoDAAC	NA
LPO DoDAAC	NA
DCAA Auditor DoDAAC	HAA211
Other DoDAAC(s)	NA

(4) Payment request and supporting documentation. The Contractor shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation, as defined in DFARS Appendix F, (e.g. timesheets) in support of each payment request.

(5) WAWF email notifications. The Contractor shall enter the email address identified below in the “Send Additional Email Notifications” field of WAWF once a document is submitted in the system.

shannyn.scassero.civ@mail mil

(g) WAWF point of contact. (1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

karen.k.goldstein.civ@mail.mil

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of clause)

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only (b) (4). It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 22 NOV 16. The amount of the funds currently allotted may be increased by the Contracting Officer without further

concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
(b) (4)	1 NOV 16
$(b) (4)	1 NOV 17
$(b) (4)	1 NOV 18

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled "Limitation of Funds", FAR 52.232-22.
(End Local Clause)

Section H - Special Contract Requirements

USE OF ANIMALS (OCONUS)

USE OF LABORATORY ANIMALS – EXISTING AWARDS PRIOR TO APRIL 2004 (OCONUS) (June 2015) (USAMRAA)

a. The contractor or its subcontractors, are authorized to conduct research under this award involving laboratory animals for the following protocols: Protocols not identified are not approved.

b. USE OF LABORATORY ANIMALS

All laws, customs, and practices of the country in which the research is to be conducted shall be complied with insofar as use of laboratory animals is concerned. In those instances where the local laws and regulations are not in alignment with the laws and regulations of the United States and the Department of Defense, the more humane and stringent guidance will be followed. The following U.S. standards and regulations for the protection, treatment, and use of animals should be adhered to: Department of Defense Instruction 3216.01, AR 40-33 "The Use of Animals In DoD Programs," 7 U.S. Code 2131 et. seq. and 9 Code of Federal Regulations, Subchapter A, Parts 1 – 4, and that research will adhere to the principles set forth in the Guide for Care and Use of Laboratory Animals, National Research Council, 2011.

c. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS

Post-award oversight of the use of laboratory animals shall be the responsibility of the contractor's Institutional Animal Care and Use Committee (IACUC). The Principal Investigator will notify the Contracting Officer in writing of any significant changes to the proposed use of animals which was the basis for award. All changes in animal use protocols must be approved by the contractor's IACUC and the USAMRMC Animal Care and Use Review Office (ACURO) prior to initiation. In addition, the IACUC (or a representative of the institution) shall immediately notify the Contracting Officer and ACURO, in writing, of any violations of law or regulations involving animal care and/or of changes in the facility's accreditation status by the Association for the Assessment and Accreditation of Laboratory Animal care, International (AAALAC) (if applicable) and/or changes in the facility's Public Health Service (PHS) Assurance status (if applicable).

d. ANIMAL USE REPORTING

Upon request by ACURO, the contractor shall annually prepare and electronically submit the U.S. Army Medical Research and Materiel Command Animal Use Report detailing the use of all animals in the research and development sponsored by the Army.

INVESTIGATING AND REPORTING

INVESTIGATING AND REPORTING POSSIBLE SCIENTIFIC MISCONDUCT (June 2015) (USAMRAA)

a. "Misconduct" or "Misconduct in Science" is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

b. Contractors shall foster a research environment that prevents misconduct in all research and that deals forthrightly with possible misconduct associated with research for which U.S. Army Medical Research and Materiel Command funds have been provided or requested.

c. The contractor agrees to:

(1) Establish and keep current an administrative process to review, investigate, and report allegations of misconduct in science in connection with research conducted by the contractor;

(2) Comply with its own administrative process;

(3) Inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures;

(4) Take immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged; and

(5) Report to the Administrative Contracting Officer (ACO) a decision to initiate an investigation into possible scientific misconduct.

d. The contractor is responsible for notifying the ACO of appropriate action taken if at any stage of an inquiry or investigation any of the following conditions exist:

(1) An immediate health hazard is involved;

(2) There is an immediate need to protect Federal funds or equipment;

(3) A probability exists that the alleged incident will be reported publicly; or

(4) There is a reasonable indication of possible criminal violation.

PROHIBITION OF HUMAN USE

PROHIBITION OF HUMAN RESEARCH (June 2015) (USAMRAA) PROHIBITION – READ FURTHER FOR DETAILS

Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information (human data), shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the contractor. Written approval from the USAMRMC ORP is also required for any subcontractor that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information.

The contractor is required to adhere to the following reporting requirements: Submission of major modifications to the protocol, continuing review documentation, and the final report are required as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRMC ORP and the USAMRAA Contracting Office.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing non-compliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRMC ORP and the USAMRAA Contracting Office. Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

PROHIBITION OF USE OF HUMAN

PROHIBITION OF HUMAN RESEARCH, USE OF HUMAN SUBJECTS (June 2015) (USAMRAA)

PROHIBITION – READ FURTHER FOR DETAILS

a. The contractor or its subcontractors, are authorized to conduct research under this award involving humans as research subjects for the following protocols: Protocols not identified are not approved.

b. Research under this award involving the use of human subjects, to include the use of human anatomical substances or identifiable private information (human data), shall not begin until the USAMRMC's Office of Research Protections (ORP) provides authorization that the research may proceed. Written approval to begin research will be issued from the USAMRMC ORP, under separate notification to the contractor. Written approval from the USAMRMC ORP is also required for any subcontractor that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP. Complete study records shall be maintained for each human research study and shall be made available for review by representatives of the USAMRMC. Research records shall be stored in a confidential manner so as to protect the confidentiality of subject information.

The contractor is required to adhere to the following reporting requirements: Submission of major modifications to the protocol, continuing review documentation, and the final report are required as outlined in the USAMRMC ORP approval memorandum.

Unanticipated problems involving risks to subjects or others, clinical holds (voluntary or involuntary), and suspension or termination of this research by the IRB, the institution, the Sponsor, or regulatory agencies, shall be promptly reported to the USAMRMC ORP and the USAMRAA Contracting Office.

The knowledge of any pending compliance inspection/visits by the FDA, ORP, or other government agency concerning this clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions, and any instances of serious or continuing non-compliance with regulatory requirements that relate to this clinical investigation or research, shall be reported immediately to the USAMRMC ORP and the USAMRAA Contracting Office. Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

PROHIBITION OF LABORATORY

PROHIBITION OF USE OF LABORATORY ANIMALS (June 2015) (USAMRAA) PROHIBITION – READ FURTHER FOR DETAILS

Notwithstanding any other terms and conditions contained in this award or incorporated by reference herein, the contractor is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the USAMRMC, Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRMC ACURO to the contractor with a copy to the USAMRAA Contracting Office. Furthermore, modifications to already approved extramural protocols require approval by ACURO prior to implementation. Once approved, notification must be given immediately to USAMRAA contracting. For each fiscal year, the contractor shall maintain, and upon request from ACURO, submit animal usage information. Non-compliance with any of these terms and conditions may result in withholding of funds and/or the terminations of the award.

PROHIBITION OF HUMAN CADAVERS

PROHIBITION OF USE OF HUMAN CADAVERS (June 2015) (USAMRAA) PROHIBITION – READ FURTHER FOR DETAILS

Research, development, testing and evaluation (RDT&E), education or training activities involving human cadaveric specimens under this award shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army mil/index.cfm?pageid=research_ protections.overview). The USAMRMC Office of Research Protections (ORP) is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail mil) for this policy. Approval must be obtained from the Head of the Army organization that is supporting/funding the activity involving cadavers as described in the Army Policy for Use of Human Cadavers. For certain activities involving cadavers, including activities supported/funded by the USAMRMC, approval must also be obtained from ORP. Award contractors must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the contractor. Non-compliance with these terms and conditions may result in withholding of funds and/or the termination of the award.

DOD CONTRACTOR TRAVEL

DOD Contractor Foreign Travel (June 2015) (USAMRAA)

Approval of Foreign Travel. Foreign travel under this contract is defined as any travel outside of the continental United States and its territories and possessions. The cost of foreign travel is allowable only when specific written approval of the Contracting Officer is obtained prior to the commencement of the travel. This is a requirement for all DoD contractors traveling on official DoD business.

1. The following requirements will be accomplished by the contractor(s) prior to foreign travel on approval of the Contracting Officer. Allow 90 days for completion of training requirements and approval of the application process. Detailed information can be found on the MRMC website: https://mrmc.amedd.army.mil/index.cfm?pageid=mrmc_resources.oconus. Select all the links under "Contractor Travel Requirements" and comply with the instructions. Consult the DoD Foreign Clearance Guide https://www fcg.pentagon mil

2. Mandatory training and minimum requirements must be met and a copy provided to the contracting officer 15 days prior to scheduled departure.

3. Costs incurred by contractor personnel on official company business, whether foreign travel and/or domestic/local travel, are allowable subject to the limitations in the Federal Acquisition Regulation (FAR clause 52.216-7 Allowable Cost and Payment); incorporated into this contract.

4. MANDATORY TRAINING – OFFICIAL GOVERNMENT TRAVEL

(a) Anti-Terrorism Level 1 (valid for one year)
(b) SERE 100 (valid for two years)
(c) PRO-File
(d) Human Rights, SOUTHCOM travel only (valid for one year)
(e) US Forces Korea, Korea travel only (valid for one year)

4.1. MINIMUM MANDATORY DOCUMENTATION

(a) USAMRMC Form 55-46 (Request for OCONUS Travel)
(b) Flight Itinerary
(c) LOA's generated through the Synchronized Pre-deployment and Operational Tracker (SPOT); completed by the responsible Contracting Officer
(d) Force Protection Plan signed by the traveler and Commanding Officer.
(e) If traveling to a Restricted or FPCON Charlie and Delta areas, the Force Protection Plan must also be signed by a GO/FO or DoD equivalent
(f) Area of responsibility briefing completed within three months of travel
(g) PACOM travel; verification that PACOM's Travel Tracker/Individual Antiterrorism Plan (TT/IATP) has been completed

(h) AFRICOM travel; verification that AFRICOM'S Theater Information Management System (TIMS) or Statement of Preparedness Document (when TIMS is not available), has been completed.

(i) USFK Form 700-19A-R-E

(j) US-ROK SOFA IAW FAR 25.8 and USFK Regulation 700-19.

5. TRAINING LINKS

(a) Anti-Terrorism Level 1- https://atlevel1.dtic mil/at/.

(b) SERE 100 - https://jko.ifcom mil

(c) PRO-File – https://prmsglobal.prms.af mil/prmsconv/profile/survey/survey.aspx

(d) Human Rights - https://www.americasnet.org.

(e) US Forces Korea - https://www.usfk mil

KEY PERSONNEL

KEY PERSONNEL (June 2015) (USAMRAA)

a. The Contractor agrees to utilize the following Key Personnel on this contract :

(b) (4), (b) (6)

[redacted]

b. The above Key Personnel shall be utilized as necessary to fulfill the requirements of this contract.

c. The contractor must provide thorough and detailed documentation of the experience, abilities, and background for Key Personnel under this contract in the form of resumes or equivalent statements of qualifications. Such documentation shall include but not be limited to: name, curriculum vitae, type and description of experience.

d. The contractor agrees that during the contract performance period substitution for Key Personnel shall not be permitted unless such substitution is necessitated by sudden illness, death, or termination of employment. In any of these events, the contractor shall promptly notify the Contracting Officer and provide the information required by paragraph (e) below.

e. All requests for substitutions must provide a detailed explanation of the circumstances necessitating the proposed substitution(s), a complete resume for the proposed substitute(s), and any other information requested by the Contracting Officer needed to approve or disapprove the proposed substitution(s). All proposed substitutes shall have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Contracting Officer or his authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

f. If any of the listed Key Personnel are subcontractor personnel, the contractor shall include the substance of this clause in any subcontract which he awards under this contract.

REPORTS, MANUSCRIPTS & REPORTS
REPORTS, MANUSCRIPTS AND PUBLIC RELEASES (June 2015) (USAMRAA)

a. Contractors are encouraged to publish results of research supported by the US Army Medical Research and Materiel Command (USAMRMC) in appropriate media forum. Any publication, report or public release, which may create a statutory bar to the issuance of a patent on any subject invention, shall be coordinated with appropriate patent counsel.

b. Manuscripts intended for publication in any media shall be submitted to the Contracting Officer and Contracting Officer's Representative (COR), simultaneously with submission for publication. Review of such manuscripts is for comment to the Principal Investigator, not for approval or disapproval. Courtesy copies of the reprint shall be forwarded to the Contracting Officer and COR, even though publication may be subsequent to the expiration of the contract.

c. The Contractor shall notify the Contracting Officer of planned news releases, planned publicity, advertising material concerning contract work, and planned presentations to scientific meetings, prior to public release. This is not intended to restrict dissemination of research information but to allow USAMRMC advance notice in order to adequately respond to inquiries.

d. Manuscripts, reports, public releases and abstracts, which appear in professional journals, media and programs, shall include the following statements:

(l) "This work is supported by the US Army Medical Research and Materiel Command under Contract No.W81XWH-16-C-0002"

(2) "The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation."

(3) As applicable, if the research involves the use of animals, the Contractor must include the following statement: "In conducting research using animals, the investigator(s) adhered to the Animal Welfare Act Regulations and other Federal statutes relating to animals and experiments involving animals and the principles set forth in the current version of the Guide for Care and Use of Laboratory Animals, National Research Council."

(4) As applicable, if the research involves human use, the Contractor must include the following statement: "In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects)."

(5) As applicable, if the research involves the use of recombinant DNA, the Contractor must include the following statement: "In conducting work involving the use of recombinant DNA the investigator(s) adhered to the current version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules."

CLAUSES INCORPORATED BY FULL TEXT

GOOD LABORATORY PRACTICES (DEC 2006) (USAMRAA)

The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of

the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

GOOD LABORATORY PRACTICES – ALTERNATE I (DEC 2006) (USAMRAA)

a. The conduct of studies on investigational new drugs or devices shall comply with the GOOD LABORATORY PRACTICE (GLP) FOR NONCLINICAL LABORATORY STUDIES regulations 21 CFR 58. The contractor shall notify the Administrative Contracting Officer by telephone immediately upon announcement by a representative of the Food and Drug Administration (FDA) of an inspection of studies performed under this contract. In addition to the FDA representative, the Contracting Officer's Representative (COR) shall have access to the contractor's records and specimens. With reference to paragraph 58.195(h) of the GLP regulations, the contractor shall notify the COR, in writing in addition to the FDA, should the contractor go out of business and/or transfer the records during the periods prescribed in paragraph 58.195. On expiration or termination of the contract, the contractor shall notify the COR of any remaining unused test articles.

b. The studies on health effects, environmental effects, and chemical fate testing required by this contract shall comply with the GOOD LABORATORY PRACTICE STANDARDS regulations. These regulations should assure the quality and integrity of data submitted pursuant to Section 4 of the Toxic Substances Control Act (TSCA). The contractor shall notify the Contracting Officer by telephone immediately upon announcement by a representative of the Environmental Protection Agency (EPA) of an inspection of studies performed under this contract. In addition to the EPA representative, the Contracting Officer's Representative shall have access to all experimental and contractual records. Archiving of test articles, records, tissues and specimens is the responsibility of the contractor.

CURRENT GOOD MANUFACTURING PRACTICES (DEC 2006) (USAMRAA)

The drug or biological drug products required by this contract shall be developed and produced in compliance with the CURRENT GOOD MANUFACTURING PRACTICE (CGMP) FOR FINISHED PHARMACEUTICALS regulations for parenteral products, 21 CFR, Part 211. Results of routine FDA inspections for licensed facilities as recorded on Form FDA 482 shall be supplied to the Contracting Officer's Representative and become part of the contract file.

52.035-4030 CONTRACTOR SAFETY AND REPORTING (NON-BDRP) (DEC 2006) (USAMRAA)

a. The contractor shall operate under established safety programs for all biosafety levels of work as identified in the Safety Program Plan, which is incorporated in this contract. The safety programs shall ensure that personnel, facilities, and the environment are protected from accidents and hazardous exposures.
b. The contractor shall conduct this contract work under established operating procedures which ensure that all individuals who have access to areas for storage, handling, and disposal of etiologic agents are trained and are thoroughly familiar with safety requirements. Such procedures shall assure full compliance with the regulatory standards cited above.
c. The contractor shall conduct an inspection and report the results of all required biosafety inspections for all Research, Development, Test, or Evaluation work in accordance with the below listed timeframes. As a minimum the safety inspections shall address those factors identified in the Safety Program Plan.

1. For Biosafety Level (BL) 1 and 2:

Time	Inspector
Preaward	Government designated Biosafety Officer
Quarterly	Contractor safety personnel
Weekly	First line supervisor

2. For Biosafety Level (BL) 3:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

3. For Biosafety Level (BL) 4:

Time	Inspector
Preaward	Government designated Biosafety Officer
Monthly	Contractor safety personnel
Annual	Government designated Biosafety Officer
Weekly	First line supervisor

4. Copies of all biosafety inspection reports will be distributed as follows:

Original: In the contractor's records

One copy to the following:

a. US Army Medical Research and Materiel Command
ATTN: MCMR-ZC-SSE
504 Scott Street
Fort Detrick, Maryland 21702-5012

b. US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-DRI
504 Scott Street
Fort Detrick, Maryland 21702-5012

c. US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-SD4
820 Chandler Street
Fort Detrick, Maryland 21702-5014

USE OF HUMAN SUBJECTS (FEB 2002) (USAMRAA)

a. The contractor or its subcontractors, are authorized to conduct research under this award involving humans as research subjects for the following protocols:

Protocols not identified are not approved.

b. Contractors and subcontractors are required to submit documentation of IRB review of protocols and consent forms from each of the funded institutions. Research at funded institutions may not begin until the U.S.

Army Surgeon General's Human Subjects Research Review Board (HSRRB) approves the protocol and consent form for that site. Review by the HSRRB is separate from, and in addition to, review by any other IRB. Contractors will be notified in writing of HSRRB approval or disapproval.

c. Contractors and subcontractors who enroll additional unfunded institutions are responsible to ensure that the institute conducts research in accordance with 45 CFR 46 and other applicable federal and state regulations. Prior to inclusion of any unfunded institution's participation under this award, the contractor is responsible to notify the Contracting Officer.

d. Volunteer Registry Data Sheet (USAMRDC Form 60-R). In accordance with the "Use of Human Subjects" provision above, the Volunteer Registry Data Sheet, USAMRDC Form 60-R (form available on web site http://www.usamraa.army.mil)is to be completed at the time the subject consents to participate and is entered into the study. The form shall be submitted to the Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012 upon completion of the research project or upon expiration/termination of the award, whichever occurs first.

e. Unless the research has been ruled exempt from the requirements of the Federal Common Rule (32 CFR 219) by the HSRRB, the local IRB is required to conduct continuing review of the contractor's research at least annually, or more often if the local IRB deems it necessary, in accordance with the Federal Common Rule. Pursuant to Office for Human Research Protections guidance, contractors must submit the following to the local IRB for continuing review: a protocol summary and status report on the progress of the research, including (1) the number of subjects accrued; (2) a description of any adverse events or unanticipated problems involving risks to subjects or other and of any withdrawal of subjects from the research or complaints about the research; (3) a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trails and any other relevant information, especially information about risks associated with the research; and (4) a copy of the current informed consent document. **Contractors are required to submit all continuing review reports, and the final report approved by the local IRB, to the HSRRB within seven working days of each review. Submissions to the HSRRB should be sent to: Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012. Submissions may also be faxed to:** (b) (6) **(ATTN: MCMR-RCQ-HR).**

f. The contractor must submit any proposed modifications or amendments to the protocol or consent form to both the local IRB and the HSRRB for review and approval. A change of the Principal Investigator is considered to be a modification of the protocol. Research pursuant to such modifications or amendments may not be initiated without IRB and HSRRB approval except when necessary to eliminate apparent immediate hazards to the subject(s).

g. Single Project Assurance. The contractor's Single Project Assurance, dated _____, is incorporated by reference and is assigned number _____.

USE OF LABORATORY ANIMALS (CONUS)(MAR 2002) (USAMRAA)

a. The contractor or its subcontractors, are authorized to conduct research under this award involving laboratory animals for the following protocols:

Protocols not identified are not approved.

b. ANIMAL WELFARE

(1) For those facilities that are required to do so by federal law, the contractor shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2136 and 9 CFR, Subchapter A, Part 2, Subpart C, and Section 2.30.

(2) The contractor shall acquire regulated animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR, Subchapter A, Part 2, Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(3) The contractor agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 et.seq. and 9 CFR Subchapter A, Parts 1 through 4), and that the research will adhere to the principles set forth in the Guide for Care and Use of Laboratory Animals, National Research Council, 1996.

(4) The Contracting Officer may immediately suspend, in whole or in part, work and further payments under this award for failure to comply with the requirements of paragraphs (1) through (3) of this clause.

(a) The suspension will stay in effect until the contractor complies with the requirements.

(b) Failure to complete corrective action within the time specified by the Contracting Officer may result in termination of this award and removal of the contractor's name from the list of facilities approved for funding.

(5) The contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Animal Care, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 (Phone number (b) (6)

(6) The contractor shall include this clause, including this paragraph (6), in all subcontracts/subawards involving research of live vertebrate animals.

c. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS

Post-award oversight of the use of laboratory animals shall be the responsibility of the contractor's Animal Care and Use Committee (ACUC). The Principal Investigator will notify the Contracting Officer in writing of any significant changes to the proposed use of animals which was the basis for award. These changes must be approved by the contractor's ACUC and the USAMRMC. In addition, the ACUC shall immediately notify the Contracting Officer of any violations of law, or regulation involving animal care, or of changes in the facility's accreditation status by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

d. ANIMAL USE REPORTING

(1) The contractor shall annually prepare and electronically submit the U.S. Army Medical Research and Materiel Command Animal Use Report detailing the use of animals in the research and development sponsored by the Army. The web site containing information for electronic submission of this report may be found at http://www.usamraa.army.mil.

(2) A letter with additional instructions concerning use of the electronic web site will be mailed at the end of the fiscal year. The reporting period shall be each Federal Fiscal Year, i.e., 01 October through 30 September, and the report shall be electronically received by the U. S. Army Medical Research and Materiel Command **no later than 1 December of that year**.

(3) For awards with expiration dates prior to 30 September, instructions for submission of the final animal use report may be found at http://www.usamraa.army mil.

(4) The contractor shall also furnish a copy of the most recent USDA Inspection Report. This report can be submitted via fax or mail to:

Commander
U.S. Army Medical Research & Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick MD 21702-5012
FAX: (b) (4), (b) (6)

(5) The contractor is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report and USDA Inspection Report be submitted for any subcontract/subaward facility).

PROPERTY ADMINISTRATOR (MAR 1999) (USAMRAA)

The designated property administrator for Government property acquired for use under this contract is Willie Jenkins.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	NOV 2013
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	MAY 2014
52.203-13	Contractor Code of Business Ethics and Conduct	APR 2010
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	APR 2014
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUL 2013
52.204-13	System for Award Management Maintenance	JUL 2013
52.204-14	Service Contract Reporting Requirements	JAN 2014
52.204-16	Commercial and Government Entity Code Reporting	NOV 2014
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.219-14	Limitations On Subcontracting	NOV 2011
52.222-50	Combating Trafficking in Persons	MAR 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.224-1	Privacy Act Notification	APR 1984
52.224-2	Privacy Act	APR 1984
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-14	Rights in Data--General	MAY 2014
52.227-17	Rights In Data-Special Works	DEC 2007
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-20	Limitation Of Cost	APR 1984
52.232-24	Prohibition of Assignment of Claims	MAY 2014
52.232-25	Prompt Payment	JUL 2013
52.232-25 Alt I	Prompt Payment (July 2013) Alternate I	FEB 2002
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	JUL 2013
52.233-1 Alt I	Disputes (May 2014) - Alternate I	DEC 1991
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.237-3	Continuity Of Services	JAN 1991
52.242-3	Penalties for Unallowable Costs	MAY 2014
52.242-13	Bankruptcy	JUL 1995
52.242-15	Stop-Work Order	AUG 1989
52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.243-2	Changes--Cost-Reimbursement	AUG 1987
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	OCT 2015
52.245-1	Government Property	APR 2012
52.245-9	Use And Charges	APR 2012

52.246-5	Inspection Of Services Cost-Reimbursement	APR 1984
52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001
52.246-8 Alt I	Inspection Of Research And Development-Cost Reimbursement (May 2001) - Alternate I	APR 1984
52.246-23	Limitation Of Liability	FEB 1997
52.247-34	F.O.B. Destination	NOV 1991
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.252-2	Clauses Incorporated By Reference	FEB 1998
52.252-4	Alterations in Contract	APR 1984
52.252-6	Authorized Deviations In Clauses	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7004	Display of Fraud Hotline Poster(s)	JAN 2015
252.204-7008 (Dev)	Compliance with Safeguarding Covered Defense Information Controls	OCT 2015
252.204-7009	Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information	AUG 2015
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting.	SEP 2015
252.204-7012 (Dev)	Safeguarding Covered Defense Information and Cyber Incident Reporting	OCT 2015
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2014
252.227-7013 Alt I	Rights in Technical Data--Noncommercial Items (FEB 2014) - Alternate I	JUN 1995
252.227-7013 Alt II	Rights in Technical Data--Noncommercial Items (FEB 2014) Alternate II	MAR 2011
252.227-7022	Government Rights (Unlimited)	MAR 1979
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	JUN 2012
252.232-7007	Limitation Of Government's Obligation	APR 2014
252.232-7008	Assignment of Claims (Overseas)	JUN 1997
252.235-7004	Protection of Human Subjects	JUL 2009
252.242-7005	Contractor Business Systems	FEB 2012
252.242-7006	Accounting System Administration	FEB 2012
252.244-7000	Subcontracts for Commercial Items	JUN 2013
252.244-7001	Contractor Purchasing System Administration	MAY 2014

CLAUSES INCORPORATED BY FULL TEXT

52.203-14 DISPLAY OF HOTLINE POSTER(S) (DEC 2007)

(a) Definition.

United States, as used in this clause, means the 50 States, the District of Columbia, and outlying areas.

(b) Display of fraud hotline poster(s). Except as provided in paragraph (c)--

(1) During contract performance in the United States, the Contractor shall prominently display in common work areas within business segments performing work under this contract and at contract work sites--

(i) Any agency fraud hotline poster or Department of Homeland Security (DHS) fraud hotline poster identified in paragraph (b)(3) of this clause; and

(ii) Any DHS fraud hotline poster subsequently identified by the Contracting Officer.

(2) Additionally, if the Contractor maintains a company website as a method of providing information to employees, the Contractor shall display an electronic version of the poster(s) at the website.

(3) Any required posters may be obtained as follows:

Poster(s) Obtain from

http://www.oig.doc.gov/Pages/Hotline.aspx

(c) If the Contractor has implemented a business ethics and conduct awareness program, including a reporting mechanism, such as a hotline poster, then the Contractor need not display any agency fraud hotline posters as required in paragraph (b) of this clause, other than any required DHS posters.

(d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts that exceed $5,000,000, except when the subcontract--

(1) Is for the acquisition of a commercial item; or

(2) Is performed entirely outside the United States.

(End of clause)

52.204-1 APPROVAL OF CONTRACT (DEC 1989)

This contract is subject to the written approval of the Contracting Officer and shall not be binding until so approved.

(End of clause)

52.216-7 ALLOWABLE COST AND PAYMENT (JUN 2013)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the 30th day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(iii) An adequate indirect cost rate proposal shall include the following data unless otherwise specified by the cognizant Federal agency official:

(A) Summary of all claimed indirect expense rates, including pool, base, and calculated indirect rate.

(B) General and Administrative expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts).

(C) Overhead expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) for each final indirect cost pool.

(D) Occupancy expenses (intermediate indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) and expense reallocation to final indirect cost pools.

(E) Claimed allocation bases, by element of cost, used to distribute indirect costs.

(F) Facilities capital cost of money factors computation.

(G) Reconciliation of books of account (i.e., General Ledger) and claimed direct costs by major cost element.

(H) Schedule of direct costs by contract and subcontract and indirect expense applied at claimed rates, as well as a subsidiary schedule of Government participation percentages in each of the allocation base amounts.

(I) Schedule of cumulative direct and indirect costs claimed and billed by contract and subcontract.

(J) Subcontract information. Listing of subcontracts awarded to companies for which the contractor is the prime or upper-tier contractor (include prime and subcontract numbers; subcontract value and award type; amount claimed during the fiscal year; and the subcontractor name, address, and point of contact information).

(K) Summary of each time-and-materials and labor-hour contract information, including labor categories, labor rates, hours, and amounts; direct materials; other direct costs; and, indirect expense applied at claimed rates.

(L) Reconciliation of total payroll per IRS form 941 to total labor costs distribution.

(M) Listing of decisions/agreements/approvals and description of accounting/organizational changes.

(N) Certificate of final indirect costs (see 52.242-4, Certification of Final Indirect Costs).

(O) Contract closing information for contracts physically completed in this fiscal year (include contract number, period of performance, contract ceiling amounts, contract fee computations, level of effort, and indicate if the contract is ready to close).

(iv) The following supplemental information is not required to determine if a proposal is adequate, but may be required during the audit process:

(A) Comparative analysis of indirect expense pools detailed by account to prior fiscal year and budgetary data.

(B) General organizational information and limitation on allowability of compensation for certain contractor personnel. See 31.205-6(p). Additional salary reference information is available at http://www.whitehouse.gov/omb/procurement_index_exec_comp/.

(C) Identification of prime contracts under which the contractor performs as a subcontractor.

(D) Description of accounting system (excludes contractors required to submit a CAS Disclosure Statement or contractors where the description of the accounting system has not changed from the previous year's submission).

(E) Procedures for identifying and excluding unallowable costs from the costs claimed and billed (excludes contractors where the procedures have not changed from the previous year's submission).

(F) Certified financial statements and other financial data (e.g., trial balance, compilation, review, etc.).

(G) Management letter from outside CPAs concerning any internal control weaknesses.

(H) Actions that have been and/or will be implemented to correct the weaknesses described in the management letter from subparagraph G) of this section.

(I) List of all internal audit reports issued since the last disclosure of internal audit reports to the Government.

(J) Annual internal audit plan of scheduled audits to be performed in the fiscal year when the final indirect cost rate submission is made.

(K) Federal and State income tax returns.

(L) Securities and Exchange Commission 10-K annual report.

(M) Minutes from board of directors meetings.

(N) Listing of delay claims and termination claims submitted which contain costs relating to the subject fiscal year.

(O) Contract briefings, which generally include a synopsis of all pertinent contract provisions, such as: Contract type, contract amount, product or service(s) to be provided, contract performance period, rate ceilings, advance approval requirements, pre-contract cost allowability limitations, and billing limitations.

(v) The Contractor shall update the billings on all contracts to reflect the final settled rates and update the schedule of cumulative direct and indirect costs claimed and billed, as required in paragraph (d)(2)(iii)(I) of this section, within 60 days after settlement of final indirect cost rates.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates. The completion invoice or voucher shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice or voucher and providing status of subcontractor audits to the contracting officer upon request.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(5) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.217-7 OPTION FOR INCREASED QUANTITY--SEPARATELY PRICED LINE ITEM (MAR 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 60 days of contract expiration. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of clause)

52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of contract expiration.

(End of clause)

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days of contract expiration; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5

years.

(End of clause)

52.230-3 DISCLOSURE AND CONSISTENCY OF COST ACCOUNTING PRACTICES (MAY 2014)

(a) The Contractor, in connection with this contract, shall--

(1) Comply with the requirements of 48 CFR 9904.401, Consistency in Estimating, Accumulating, and Reporting Costs; 48 CFR 9904.402, Consistency in Allocating Costs Incurred for the Same Purpose; 48 CFR 9904.405, Accounting for Unallowable Costs; and 48 CFR 9904.406, Cost Accounting Standard--Cost Accounting Period, in effect on the date of award of this contract as indicated in 48 CFR Part 9904.

(2) (CAS-covered Contracts Only) If it is a business unit of a company required to submit a Disclosure Statement, disclose in writing its cost accounting practices as required by 48 CFR 9903.202-1 through 9903.202-5. If the Contractor has notified the Contracting Officer that the Disclosure Statement contains trade secrets and commercial or financial information which is privileged and confidential, the Disclosure Statement shall be protected and shall not be released outside of the Government.

(3)(i) Follow consistently the Contractor's cost accounting practices. A change to such practices may be proposed, however, by either the Government or the Contractor, and the Contractor agrees to negotiate with the Contracting Officer the terms and conditions under which a change may be made. After the terms and conditions under which the change is to be made have been agreed to, the change must be applied prospectively to this contract, and the Disclosure Statement, if affected, must be amended accordingly.

(ii) The Contractor shall, when the parties agree to a change to a cost accounting practice and the Contracting Officer has made the finding required in 48 CFR 9903.201-6(c), that the change is desirable and not detrimental to the interests of the Government, negotiate an equitable adjustment as provided in the Changes clause of this contract. In the absence of the required finding, no agreement may be made under this contract clause that will increase costs paid by the United States.

(4) Agree to an adjustment of the contract price or cost allowance, as appropriate, if the Contractor or a subcontractor fails to comply with the applicable CAS or to follow any cost accounting practice, and such failure results in any increased costs paid by the United States. Such adjustment shall provide for recovery of the increased costs to the United States together with interest thereon computed at the annual rate established under section 6621(a)(2) of the Internal Revenue Code of 1986 (26 U.S.C. 6621(a)(2)), from the time the payment by the United States was made to the time the adjustment is effected.

(b) If the parties fail to agree whether the Contractor has complied with an applicable CAS, rule, or regulation as specified in 48 CFR 9903 and 9904 and as to any cost adjustment demanded by the United States, such failure to agree will constitute a dispute under 41 U.S.C. chapter 71, Contract Disputes.

(c) The Contractor shall permit any authorized representatives of the Government to examine and make copies of any documents, papers, and records relating to compliance with the requirements of this clause.

(d) The Contractor shall include in all negotiated subcontracts, which the Contractor enters into, the substance of this clause, except paragraph (b), and shall require such inclusion in all other subcontracts of any tier, except that--

(1) If the subcontract is awarded to a business unit which pursuant to 48 CFR 9903.201-2 is subject to other types of CAS coverage, the substance of the applicable clause set forth in subsection 30.201-4 of the Federal Acquisition Regulation shall be inserted.

(2) This requirement shall apply only to negotiated subcontracts in excess of $700,000.

(3) The requirement shall not apply to negotiated subcontracts otherwise exempt from the requirement to include a CAS clause as specified in 48 CFR 9903.201-1.

(End of clause)

52.243-2 CHANGES--COST-REIMBURSEMENT (AUG 1987) - ALTERNATE II (APR 1984)

(a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:

(1) Description of services to be performed.

(2) Time of performance (i.e., hours of the day, days of the week, etc.).

(3) Place of performance of the services.

(4) Drawings, designs, or specifications when the supplies to be furnished are to be specially manufactured for the Government in accordance with the drawings, designs, or specifications.

(5) Method of shipment or packing of supplies.

(6) Place of delivery.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the (1) estimated cost, delivery or completion schedule, or both; (2) amount of any fixed fee; and (3) other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) above, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

52.243-2 CHANGES--COST-REIMBURSEMENT (AUG 1987) - ALTERNATE V (APR 1984)

(a) The Contracting Officer may at any time, by written order, and without notice to the sureties, if any, make changes within the general scope of this contract in any one or more of the following:

(1) Drawings, designs, or specifications.

(2) Method of shipment or packing.

(3) Place of inspection, delivery, or acceptance.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the (1) estimated cost, delivery or completion schedule, or both; (2) amount of any fixed fee; and (3) other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) above, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

52.243-7 NOTIFICATION OF CHANGES (APR 1984)

(a) Definitions.

"Contracting Officer," as used in this clause, does not include any representative of the Contracting Officer.

"Specifically authorized representative (SAR)," as used in this clause, means any person the Contracting Officer has so designated by written notice (a copy of which shall be provided to the Contractor) which shall refer to this subparagraph and shall be issued to the designated representative before the SAR exercises such authority.

(b) Notice. The primary purpose of this clause is to obtain prompt reporting of Government conduct that the Contractor considers to constitute a change to this contract. Except for changes identified as such in writing and signed by the Contracting Officer, the Contractor shall notify the Administrative Contracting Officer in writing, within three (3) calendar days from the date that the Contractor identifies any Government conduct (including actions, inactions, and written or oral communications) that the Contractor regards as a change to the contract terms and conditions. On the basis of the most accurate information available to the Contractor, the notice shall state--

(1) The date, nature, and circumstances of the conduct regarded as a change;

(2) The name, function, and activity of each Government individual and Contractor official or employee involved in or knowledgeable about such conduct;

(3) The identification of any documents and the substance of any oral communication involved in such conduct;

(4) In the instance of alleged acceleration of scheduled performance or delivery, the basis upon which it arose;

(5) The particular elements of contract performance for which the Contractor may seek an equitable adjustment under this clause, including--

(i) What contract line items have been or may be affected by the alleged change;

(ii) What labor or materials or both have been or may be added, deleted, or wasted by the alleged change;

(iii) To the extent practicable, what delay and disruption in the manner and sequence of performance and effect on continued performance have been or may be caused by the alleged change;

(iv) What adjustments to contract price, delivery schedule, and other provisions affected by the alleged change are estimated; and

(6) The Contractor's estimate of the time by which the Government must respond to the Contractor's notice to minimize cost, delay or disruption of performance.

(c) Continued performance. Following submission of the notice required by (b) above, the Contractor shall diligently continue performance of this contract to the maximum extent possible in accordance with its terms and conditions as construed by the Contractor, unless the notice reports a direction of the Contracting Officer or a communication from a SAR of the Contracting Officer, in either of which events the Contractor shall continue performance; provided, however, that if the Contractor regards the direction or communication as a change as described in (b) above, notice shall be given in the manner provided. All directions, communications, interpretations, orders and similar actions of the SAR shall be reduced to writing and copies furnished to the Contractor and to the Contracting Officer. The Contracting Officer shall countermand any action which exceeds the authority of the SAR.

(d) Government response. The Contracting Officer shall promptly, within ten (10) calendar days after receipt of notice, respond to the notice in writing. In responding, the Contracting Officer shall either--

(1) Confirm that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance;

(2) Countermand any communication regarded as a change;

(3) Deny that the conduct of which the Contractor gave notice constitutes a change and when necessary direct the mode of further performance; or

(4) In the event the Contractor's notice information is inadequate to make a decision under (1), (2), or (3) above, advise the Contractor what additional information is required, and establish the date by which it should be furnished and the date thereafter by which the Government will respond.

(e) Equitable adjustments.

(1) If the Contracting Officer confirms that Government conduct effected a change as alleged by the Contractor, and the conduct causes an increase or decrease in the Contractor's cost of, or the time required for, performance of any part of the work under this contract, whether changed or not changed by such conduct, an equitable adjustment shall be made--

(i) In the contract price or delivery schedule or both; and

(ii) In such other provisions of the contract as may be affected.

(2) The contract shall be modified in writing accordingly. In the case of drawings, designs or specifications which are defective and for which the Government is responsible, the equitable adjustment shall include the cost and time

extension for delay reasonably incurred by the Contractor in attempting to comply with the defective drawings, designs or specifications before the Contractor identified, or reasonably should have identified, such defect. When the cost of property made obsolete or excess as a result of a change confirmed by the Contracting Officer under this clause is included in the equitable adjustment, the Contracting Officer shall have the right to prescribe the manner of disposition of the property. The equitable adjustment shall not include increased costs or time extensions for delay resulting from the Contractor's failure to provide notice or to continue performance as provided, respectively, in (b) and (c) above.

Note: The phrases “contract price” and “cost” wherever they appear in the clause, may be appropriately modified to apply to cost-reimbursement or incentive contracts, or to combinations thereof.

(End of clause)

52.244-2 SUBCONTRACTS (OCT 2010)

(a) Definitions. As used in this clause--

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that—

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer’s written consent before placing the following subcontracts:

Any subcontracts not listed below and/or approved by the Contracting Officer in writing.

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor's current, complete, and accurate certified cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting—

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason certified cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's certified cost or pricing data in determining
the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's certified cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination—

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the

Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

(b) (4) [redacted]

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

LIST OF ATTACHMENTS
ATTACHMENT A – QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)
CONTRACT DATA REQUIREMENTS LIST (CDRL)
CDRL B001 – Contract Work Breakdown Structure (CWBS)
CDRL B002 – Integrated Master Schedule (IMS)
CDRL B003 – Quarterly Progress Reports (QPR)
CDRL B004 – Quality Management Plan (QMP)
CDRL B005 – Final Clinical Study Report
CDRL B006 – Final Bioequivalence Study Report
CDRL B007 – Final Common Technical Document (CTD) & electronic Common Technical Document (eCTD)
CDRL B008 – Active Pharmaceutical Ingrediients (API) Manufacturing Documents
CDRL B009 – Stability Reports (SRs)
CDRL B010 – Final Non-Clinical Study Report
CDRL B011 – Pre-Submission Package
CDRL B012 – New Drug Application Submission (NDA Submission)
CDRL B013 – Market Analysis

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00001	16-Dec-2015	0010653494-0003	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
CODE 4ANW8 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 19-Nov-2015

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☒ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: lcrumba161123

The purposes of this modification are to:

1. Add missing CLIN details (PSC, NAICS, SIC, etc) to the contract CLINs; and,
2. Add missing clauses prescribed by DFARS.

All other terms and conditions remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) [redacted] mail mil
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNE (Signature of Contracting Officer)	16C. DATE SIGNED 10-Dec-2015

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002
The FSC code AN93 has been added.
The PROG code S10 has been added.
The WSC Equipment code 000 has been added.
The SIC code 8731 has been added.
The NAICS code 541711 has been added.
The MDAP/MAIS Code 000 has been added.

CLIN 0003
The FSC code AN93 has been added.
The PROG code S10 has been added.
The WSC Equipment code 000 has been added.
The SIC code 8731 has been added.
The NAICS code 541711 has been added.
The MDAP/MAIS Code 000 has been added.

CLIN 0004
The FSC code AN93 has been added.
The PROG code S10 has been added.
The WSC Equipment code 000 has been added.
The SIC code 8731 has been added.
The NAICS code 541711 has been added.
The MDAP/MAIS Code 000 has been added.

SUBCLIN 000401
The PROG code S10 has been added.
The SIC code 8731 has been added.
The NAICS code 541711 has been added.
The MDAP/MAIS Code 000 has been added.

SECTION I - CONTRACT CLAUSES

The following have been added by reference:

252.203-7003	Agency Office of the Inspector General	DEC 2012
252.211-7007	Reporting of Government-Furnished Property	AUG 2012
252.245-7001	Tagging, Labeling, and Marking of Government-Furnished	APR 2012

	Property	
252.245-7002	Reporting Loss of Government Property	APR 2012
252.245-7003	Contractor Property Management System Administration	APR 2012
252.245-7004	Reporting, Reutilization, and Disposal	MAR 2015

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00002	12-Feb-2016	0010653494-0003	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.232-20, Limitation of Cost.

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: lcrumba162017

The purposes of this modification are to:

1. Recognize a cost/fee reduction on CLIN0001,
2. Deobligate CLIN0001 funding associated with the cost reduction,
3. Recognize an increase in the estimated cost/fee for option CLIN0002 and option CLIN0003, and
4. Make administrative changes as described in the Summary of Changes section.

All other terms and conditions remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	BARRY G. SAYER / CONTRACTING OFFICER TEL: (301) 619-2375 EMAIL: barryg.sayer.civ@mail.mil

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16C. DATE SIGNED
(Signature of person authorized to sign)	(b) (6)	17-Feb-2016

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by $(b) (4) from $(b) (4) to $6,311,211.00.

The following have been modified:

ADDITIONAL INFORMATION

Project Title: Support for the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)

This requirement is an R&D Service.

The NAICS code for this solicitation is 541711 (Research and Development Biotechnology).

The Government herein awards a Cost Plus Fixed Fee (CPFF) Contract

The base period of performance (POP) shall be four (4) years.

This contract is awarded in accordance with FAR 6.203, Full and Open Competition after Exclusion of Sources, Set Asides for Small Business Concerns.

Fast Track's Revised Technical Proposal dated 14 JAN 16 and Revised Cost Proposal dated 29 JAN 16 are incorporated by reference.

The Government Points of Contract are as follows:

Contracting Officer: Barry G. Sayer at 301-619-2375 or barry.g.sayer.civ@mail mil

Contract Specialist: Lucas Crumbacker at 301-619-7806 or lucas r.crumbacker.civ@mail mil

Contracting Officer's Representative: LTC (b) (6)

FREEDOM OF INFORMATION ACT (FOIA) INQUIRIES

U.S. Army Medical Research Acquisition Activity (USAMRAA)
ATTN: MRMC-AAP-A/Nancy Gaynor
820 Chandler Street
Fort Detrick, MD 21702-5014
E-mail: nancy.gaynor.civ@mail.mil
301-619-2389

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U. S. Army Medical Research and Materiel Command (USAMRMC)". The Contractor's proposal dated 28 SEP 15 and budget dated 9 OCT 15 are incorporated by reference. POP: 4 Years

To:

The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U. S. Army Medical Research and Materiel Command (USAMRMC)". The Contractor's revised technical proposal dated 14 JAN 16 and revised budget dated 04 FEB 16 are incorporated by reference. POP: 4 Years.

The estimated/max cost has decreased by $(b) (4) from $(b) (4) to $(b) (4)
The fixed fee has decreased by $(b) (4) from $(b) (4) to $(b) (4)
The total cost of this line item has decreased by $(b) (4) from $(b) (4) to $(b) (4)

CLIN 0002

The CLIN extended description has changed from:

The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)", PARA 4.5. The Contractor's proposal dated 28 SEP 15 and budget dated 9 OCT 15 are incorporated by reference.

To:

The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)", PARA 4.5. The Contractor's revised technical proposal dated 14 JAN 16 and revised budget dated 04 FEB 16 are incorporated by reference..

The estimated/max cost has increased by $(b) (4) from $(b) (4) to $(b) (4)
The fixed fee has increased by $(b) (4) from $(b) (4) to $(b) (4)
The total cost of this line item has increased by $(b) (4) from $(b) (4) to $(b) (4)

CLIN 0003

The CLIN extended description has changed from:

The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)", PARA 4.6. The Contractor's proposal dated 28 SEP 15 and budget dated 9 OCT 15 are incorporated by reference.

To:

The Contractor is responsible for providing all the resources necessary to support the Statement of Objectives (SOO) entitled "Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U.S. Army Medical Research and Materiel Command (USAMRMC)", PARA 4.6. The Contractor's revised technical proposal dated 14 JAN 16 and revised budget dated 04 FEB 16 are incorporated by reference..

The estimated/max cost has increased by $(b) (4) from $(b) (4) to $(b) (4)
The fixed fee has increased by $(b) from $(b) (4) to $(b) (4)

The total cost of this line item has increased by $(b) (4) from $(b) (4) to $475,335.00.

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was decreased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000102:

AB: 021201620172040000066464325 5 R.0001626.9 6100.9000021001 A74FG (CIN GFEBS001065349400006) was decreased by $(b) (4) from $(b) (4) to $(b) (4)

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 22 NOV 16. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
(b) (4)	1 NOV 16
$(b) (4)	1 NOV 17
$(b) (4)	1 NOV 18

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled "Limitation of Funds", FAR 52.232-22.
(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00003	29-Feb-2016	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
Exercise a contract option in accordance with FAR 52.217-7.

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: lcrumba162237

The purposes of this modification are to exercise and incrementally fund Option CLIN 0002.

All other terms and conditions remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) BARRY G. SAYER / CONTRACTING OFFICER TEL: (301) 619-2375 EMAIL: barryg.sayer.civ@mail.mil	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. U[redacted] BY [redacted] ([redacted]	16C. DATE SIGNED 02-Mar-2016

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $(b) (4) from $(b) (4) to $7,832,925.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002
The option status has changed from Option to Option Exercised.

SUBCLIN 000201 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000201					$0.00
	CLIN 0002 - Incremental Funding FFP FOB: Destination PURCHASE REQUEST NUMBER: 0010828327				
				NET AMT	$0.00
	ACRN AB CIN: GFEBS001082832700001				$(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000201:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000201:

Funding on SUBCLIN 000201 is initiated as follows:

ACRN: AB

CIN: GFEBS001082832700001

Acctng Data: 021201620172040000066464325 5 R.0001626.9 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be (b) (4). There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only (b) (4). It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 22 NOV 16. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
$1,386,224	1 MAY 16
$1,271,131	1 MAY 17
$1,321,186	1 MAY 18

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled “Limitation of Funds”, FAR 52.232-22.
(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00004	08-Apr-2016	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
Unilateral, USAMRAA 5152.232-9000 Incremental Funding

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: tduvall162604

The subject contract is modified for the following purpose:

Add incremental funding in the amount of $(b) (4) to the contract; $(b) (4) at CLIN 0001 and $(b) (4) at CLIN 0002. (Reference PR 0010840693).

All other terms and conditions remain unchanged. Please see 'Summary of Changes' for details.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) BARRY G. SAYER / CONTRACTING OFFICER TEL: (301) 619-2375 EMAIL: barryg.sayer.civ@mail.mil	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. U(b) (6) BY [redacted] (	16C. DATE SIGNED 05-Apr-2016

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000103 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000103					$0.00

CLIN 0001 - Incremental Funding
FFP
Amount: $(b) (4) (Reference PR 0010840693, item 0001).
FOB: Destination
PURCHASE REQUEST NUMBER: 0010840693

NET AMT $0.00

ACRN AB $(b) (4)
CIN: GFEBS001084069300001

SUBCLIN 000104 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000104					$0.00

CLIN 0001 - Incremental Funding
FFP
Amount: $(b) (4) (Reference PR 0010840693, item 0002).
FOB: Destination
PURCHASE REQUEST NUMBER: 0010840693

NET AMT $0.00

ACRN AC $(b) (4)
CIN: GFEBS001084069300002

SUBCLIN 000202 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000202					$0.00

CLIN 0002 - Incremental Funding
FFP
Amount: $(b) (4) (Reference PR 0010840693, item 0003).
FOB: Destination
PURCHASE REQUEST NUMBER: 0010840693

NET AMT $0.00

ACRN AC $(b) (4)
CIN: GFEBS001084069300003

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000103:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000104:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000202:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000103:
Funding on SUBCLIN 000103 is initiated as follows:

ACRN: AB

CIN: GFEBS001084069300001

Acctng Data: 021201620172040000066464325 5 R.0001626.9 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

SUBCLIN 000104:
Funding on SUBCLIN 000104 is initiated as follows:

ACRN: AC

CIN: GFEBS001084069300002

Acctng Data: 021201620172040000665654255 R.0001626.10 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

SUBCLIN 000202:
Funding on SUBCLIN 000202 is initiated as follows:

ACRN: AC

CIN: GFEBS001084069300003

Acctng Data: 021201620172040000665654255 R.0001626.10 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 22 NOV 17. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
~~$(b) (4)~~	~~1 MAY 16~~ ($1,486,224 sent 11 MAR 16)
$(b) (4)	1 MAY 17
$(b) (4)	1 MAY 18 (reduced by $100K to reflect higher amount sent 11 MAR 16)

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled “Limitation of Funds”, FAR 52.232-22.

(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00006	12-Jan-2017	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
USAMRAA 5152.232-9000—Incremental Funding

E. IMPORTANT: Contractor [X] is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: tkelly171264
The purpose of this modification is to incrementally fund CLIN 0002 in the amount of $[redacted]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
		BARRY G. SAYER / CONTRACTING OFFICER TEL: (301) 619-2375 EMAIL: barryg.sayer.civ@mail.mil
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. U[redacted] BY [redacted]
		16C. DATE SIGNED 12-Jan-2017

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000203 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000203					$0.00
	Funding for CLIN 0002 FFP FOB: Destination PURCHASE REQUEST NUMBER: 0010953791				
				NET AMT	$0.00
	ACRN AD CIN: GFEBS001095379100001				$(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000203:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000203:
Funding on SUBCLIN 000203 is initiated as follows:

ACRN: AD

CIN: GFEBS001095379100001

Acctng Data: 021201720182040000066565425 5 R.0001626.12 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

(b) CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00007	24-May-2017	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

(4)

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)
FAST TRACK DRUGS & BIOLOGICS LLC
(b) (6) [redacted]
5 PARAMUS CT
GAITHERSBURG MD 20878-4276

	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (SEE ITEM 11)
X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
X	10B. DATED (SEE ITEM 13) 19-Nov-2015

CODE 4ANW8 FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
FAR 52.243-4

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: tkelly172499

The purpose of this modification is to:

1. - Decrement CLIN 0002 from $(b) (4) [redacted] by $(b) (4) [redacted] to $(b) (4) [redacted],
2. - Increase CLIN 0001 from $(b) (4) [redacted] by $(b) (4) [redacted] to $[redacted]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	THEA R. MADDOX HOFGESANG / CONTRACTING OFFICER TEL: 301-619-7350 EMAIL: thea r.hofgesang.civ@mail.mil

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6) [redacted] (Signature of Contracting Officer)	24-May-2017

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001
The estimated/max cost has increased by $(b) (4) from $(b) (4) to $(b) (4)
The total cost of this line item has increased by $(b) (4) from $(b) (4) to $(b) (4)

CLIN 0002
The estimated/max cost has decreased by $(b) (4) from $(b) (4) to $(b) (4)
The total cost of this line item has decreased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000105 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000105					$0.00

Funding CLIN
FFP
Additional funding in the amount of $(b) (4) which was decremented from CLIN 0002
FOB: Destination
PURCHASE REQUEST NUMBER: 0010953791-0002

NET AMT $0.00

ACRN AD $(b) (4)
CIN: GFEBS001095379100003

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000105:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

SUBCLIN 000105:
Funding on SUBCLIN 000105 is initiated as follows:

ACRN: AD

CIN: GFEBS001095379100003

Acctng Data: 021201720182040000066565425 5 R.0001626.12 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

SUBCLIN 000203:

AD: 021201720182040000066565425 5 R.0001626.12 6100.9000021001 A74FG (CIN GFEBS001095379100001) was decreased by $(b) (4) from $(b) (4) to $(b) (4)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00007	24-May-2017	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC (b) (b) (6) 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
CODE 4ANW8 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 19-Nov-2015

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
FAR 52.243-4

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: tkelly172499

The purpose of this modification is to:

1. - Decrement CLIN 0002 from $(b) (4) by $(b) (4) to $(b) (4)
2. - Increase CLIN 0001 from $(b) (4) by $(b) (4) to $[redacted]

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) THEA R. MADDOX HOFGESANG / CONTRACTING OFFICER TEL: 301-619-7350 EMAIL: thea r.hofgesang.civ@mail.mil	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNI (b) (6) BY (Sig	16C. DATE SIGNED 24-May-2017

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001
The estimated/max cost has increased by $(b) (4) from $(b) (4) to $(b) (4)
The total cost of this line item has increased by $(b) (4) from $(b) (4) to $(b) (4)

CLIN 0002
The estimated/max cost has decreased by $(b) (4) from $(b) (4) to $(b) (4)
The total cost of this line item has decreased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000105 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000105					$0.00

Funding CLIN
FFP
Additional funding in the amount of $349,793 which was decremented from CLIN 0002
FOB: Destination
PURCHASE REQUEST NUMBER: 0010953791-0002

NET AMT $0.00

ACRN AD $(b) (4)
CIN: GFEBS001095379100003

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000105:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

SUBCLIN 000105:
Funding on SUBCLIN 000105 is initiated as follows:

ACRN: AD

CIN: GFEBS001095379100003

Acctng Data: 021201720182040000066565425 5 R.0001626.12 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

SUBCLIN 000203:

AD: 021201720182040000066565425 5 R.0001626.12 6100.9000021001 A74FG (CIN GFEBS001095379100001) was decreased by $(b) (4) from $(b) (4) to $(b) (4)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00008	11-Aug-2017	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
CODE 4ANW8 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 19-Nov-2015

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
52.243-2 CHANGES--COST-REIMBURSEMENT (AUG 1987)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: tkelly173874

The purpose of this modification is to add additional work which falls under the scope of work. All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	KELLY GREEN / CONTRACT SPECIALIST TEL: 301-619-1346 EMAIL: kellyr.green.civ@mail.mil

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. U[redacted]	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6) [redacted]	11-Aug-2017

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

D FORM 30 (Rev. 10-83)
by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:
STATEMENT OF OBJECTIVES

Statement of Objectives (SOO)

Supporting the Advancement of Tafenoquine (TQ) Product Contract for the U. S. Army Medical Materiel Development Activity (USAMMDA)

C.1.0 Objective
In direct support of the US Army product development efforts to provide a prophylaxis drug for the prevention of malaria, the Government is seeking to establish a contract to complete the activities in support of a New Drug Application (NDA) for Tafenoquine (TQ), a new antimalarial drug in advance development. This effort will enable the TQ drug development program to continue with manufacturing activities as well as studies needed for the NDA. The effort will span a period of performance of four years, which will allow for drug product to be produced, additional studies to be completed, as required, and the NDA filing to be prepared and submitted by NLT 2019.

C.2.0 Background
The TQ Integrated Product Team (IPT) is in a critical phase of the drug development. The IPT has gained considerable momentum in understanding what legacy data it has for a dossier for submission to the Food and Drug Administration (FDA) regulatory authorities. The dossier will consist of thousands of pages of tabulations, charts, summaries, analyses, and numerous reports of non-clinical and clinical studies which were completed over the past 25+ years. There is at least one additional year of compilation, tabulations, charting and analysis of legacy studies necessary to complete the dossier before a Common Technical Document (CTD) is ready for submission to the FDA. To continue ongoing activities without delay, there is need to complete the remaining development activities and prepare the electronic Common Technical Document (eCTD) for submission of TQ's dossier for marketing authorization by the FDA and the Australian Therapeutics Goods Administration (TGA).

The Government and its commercial partner, 60^{o} Pharmaceuticals, LLC, have entered into a Cooperative Research and Development Agreement (CRADA) for technology transfer of the TQ product developed by the Government. The Government's regulatory strategy is submission of a New Drug Application (NDA) to the Australian TGA, followed by a submission to the FDA. The precise timings of the drug application submissions will be by mutual consent with the overriding intent to maximize the likelihood of an FDA approval of a prophylaxis marketing authorization in the US. Submissions to Health Canada and/or European Medicines Agency (EMA) will be entirely at the discretion of the commercial partner. Ultimately, and under a separate contracting vehicle, 60° Pharmaceuticals, LLC will execute a long-term supply agreement to support the commercial marketing and distribution of TQ.

The TQ manufacturing strategy involves the Government procuring clinical product and registration batches through this proposed contract. Piramal Enterprises Limited, Healthcare Division in Mumbai, India, has developed a manufacturing process for TQ that is FDA inspected and approved for another Sponsor. Considerable time and cost savings might be gained by capitalizing on the manufacturing process established by Piramal. In addition, this specific TQ product has been qualified by the government and used in multiple clinical studies to support an NDA.

This contract will allow the Government to complete the NDA for submission to the TGA and the FDA and procure product the required non-clinical/clinical studies.

C.3.0 Period of Performance
2015 – 2019

C.4.0 Specific Tasks

C.4.1 Regulatory Support and Documentation:

C.4.1.a Prepare Common Technical Document (CTD)
The Contractor shall complete preparation activities remaining for modules 1, 2, 4 & 5 of TQ CTD required for submission to regulatory agencies. The Contractor shall provide all necessary support services to complete the remaining sections including, but not limited to, medical writing, technical support, editing and assembly of the CTD modules in paper, Non-eCTD Electronic Dossier (NeeD) or eCTD format that will comprise the NDA dossier in full compliance with the relevant regulatory requirements (DELIVERABLE No. 10/CDRL B007/QASP 7). The estimated current percent (%) completion on each Module and sub-section are:

Module 1: Administrative Information
- 1.1 Forms: 70%
- 1.2 Cover Letters: 70%
- 1.3 Administrative Information: 70%
- 1.4 References: 70%
- 1.5 Application Status: 70%
- 1.6 Meetings: 0%
- 1.7 Fast Track Request: 0%
- 1.8 Special Protocol Assessment Request: N/A
- 1.9 Pediatric Administrative Information: 0%
- 1.10 Dispute Resolution: N/A
- 1.11 Information Amendment: 70%
- 1.12 Other Correspondence: 70%
- 1.13 Annual Report: N/A
- 1.14 Labeling: 75%
- 1.15 Promotional Material: 75%
- 1.16 Risk Management Plan: 70%
- 1.17 Post-marketing Studies: 0%
- 1.18 Proprietary Names: 70%
- 1.19 Pre-EUA and EUA: 0%
- 1.20 General Investigational Plan for Initial IND: 70%

Module 2: Summaries
- 2.2 Introduction to Summary: 0%
- 2.3 Quality Overall Summary: 0%
- 2.4 Nonclinical Overview: 50%
- 2.5 Clinical Overview: 50%
- 2.6 Nonclinical Written and Tabulated Summaries: 70%
- 2.7 Clinical Summary: 70%

Module 4: Nonclinical Study Reports
- 4.2 Study Reports
- 4.2.1 Pharmacology: 70%
- 4.2.2 Pharmacokinetics: 70%
- 4.2.3 Toxicology: 70%
- 4.3 Literature References: 70%

Module 5: Clinical Study Reports
- 5.2 Tabular Listing of All Clinical Studies: 90%

5.3 Clinical Study Reports and Related Information: 70%
5.4 Literature References: 75%

C.4.1.b Prepare Electronic Common Technical Document (eCTD)
The Contractor shall provide all necessary support services to update the CTD in preparation to regulatory submission and prepare an electronic version of the dossier for submission to the regulatory agencies in full compliance with the relevant International Conference on Harmonization (ICH) CTD technical specifications and electronic submission requirements (DELIVERABLE No. 10/CDRL B007/QASP 7).

C.4.1.c Integrated CTD
The Contractor shall work closely with the TQ commercial partner (60º Pharmaceuticals, LLC, 1025 Connecticut Avenue NW, Suite 1000, Washington, D.C. 20036) and USAMMDA to write and integrate module 3 of the CTD and the Quality Summary (Module 2.3) into modules 1, 2, 4 & 5 in preparation of submission of the TQ dossier to the regulatory agencies.

C.4.1.d Organize Regulatory Pre-Submission Meeting
The Contractor shall provide writing, editing, and technical support services for the organization of a pre-NDA meeting with the regulatory agencies and preparation of meeting package (DELIVERABLE No. 15/CDRL B011/QASP 11) in full compliance with the relevant regulatory requirements. The Contractor shall also facilitate preplanning strategy sessions and rehearsals of presentations to the regulatory authorities.

C.4.1.e Manage New Drug Application Submission
The Contractor shall prepare and/or assist the TQ IPT in the production of all regulatory documents in compliance with requirements of the regulatory agencies (DELIVERABLE No. 16/CDRL B012/QASP 12). This task also includes developing and/or assisting with the development and/or review of any regulatory correspondence. The Contractor shall prepare and/or assist with communications, information requests, and preparation of meeting packages for the regulatory authorities. The content and preparation of responses shall be coordinated closely with USAMMDA's Product Manager and the commercial partner.

C.4.1 f Organize Meetings
The Contractor shall organize and host up to two CONUS and two OCONUS meetings per year with external partners and provide all the required scientific, technical, administrative, and financial support services needed for the conduct of meetings, as needed (DELIVERABLE No. 17). The number of attendees for each of the meetings is expected to be within the range of 10-20 persons. The two possible OCONUS meeting locations will be Canberra, Australia and Hyderabad, India. The CONUS meeting sites include Atlanta, GA; Philadelphia, PA; and Washington, D.C. Support services shall include travel arrangements and facilitating full participation of essential non-Government/military personnel and consultants who are needed to attend the meeting. The contractor shall generate summary reports and/or meeting minutes, as appropriate.

C.4.1.g Provide Relevant Expertise in Clinical Research and Regulatory Affairs
The Contractor shall facilitate, on an as needed basis, the identification of consultants in clinical research and regulatory affairs with broad experience in dealing with US national as well international regulatory authorities and drug licensing bodies and procure their services, either directly, or through subcontracting, to advise the TQ Product Manager and TQ IPT on the best strategies to achieve global acceptance of TQ for prophylactic indications by US and NATO forces and various relevant civilian market segments. Staff, consultants and/or contractors should have essential relevant expertise in cGLP Toxicology (est. 640 hours), Clinical Pharmacology (est. 640 hours), Ophthalmology (est. 40 hours), Malaria (est. 640 hours), Chemistry Manufacturing and Controls (CMC) (est. 640 hours) and Clinical (est. 640 hours). Staff, consultant and/or contractors shall possess the requisite education and experience in their field of expertise.

C.4.2 Prepare Market Analysis

C.4.2a Malaria Prophylaxis Market Analysis

The contractor shall provide market analysis, as needed, to assess TQ potential market size in various markets spaces such as the United States, Australia, Canada, New Zealand, and the European Union inclusive, but not limited to, Netherlands, France, United Kingdom and Germany (DELIVERABLE No. 11/CDRL B013). Market analysis shall include assessment of the corporate, public health/government and civilian travel markets. The analysis shall address current malaria chemo-prophylactic drug markets sizes, in general, and Malarone and mefloquine markets sizes, in particular. The contractor shall conduct analyses designed to assess willingness to pay using validated methodology such as the Gabor-Granger method or equivalent. The contractor shall conduct qualitative market research with a focus on the US to assess commercial trends in the use of malaria prophylactic drugs, supply chain, and access issues related to procurement of malaria drugs. The contractor shall research demographic data for short term travelers (travelers for up to 3 weeks in endemic areas) as well as long-term travelers (travelers for longer than 3 weeks in endemic areas) in the target markets and conduct market forecasts for antimalarial drugs use amongst NATO forces.

C.4.2.b G6PD Testing Market Survey
The contractor shall research the status of G6PD testing in each market space where market analysis is undertaken and each provider/distribution channel with a view to provide input into the risk management plans and pharmacovigilance standard operating procedures for each country.

C.4.3 Procure API and Produce Registration Batches of Drug Product:

C.4.3.a The Contractor shall procure cGMP TQ Active Pharmaceutical Ingredients (API) in bulk quantity needed for formulation development. The manufacturing batches should include pilot scale (if necessary) up to and including full commercial scale production lots.

C.4.3.b The Contractor shall procure cGMP TQ Active Pharmaceutical Ingredients (API) in bulk to prepare three batches of cGMP drug product suitable for registration in target markets including the USA. Fill finish activities of the material produced should be in a tablet or capsule formulation with final packaging ready for patient administration. The Contractor shall provide copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product (DELIVERABLE No. 8/CDRL B008/ QASP 2).

C.4.3.c The Contractor shall set up a stability testing program and provide stability reports (SRs) (DELIVERABLE No. 9/CDRL B009) within five (5) business days of receipt. The stability program should conform to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines for Quality, Q1A-Q1F.

C.4.3.d As stated in 2.0 Background, PARA 2, Piramal Enterprises Limited, Healthcare Division in Mumbai, India, has extensive knowledge and expertise in producing bulk lots of TQ. The current minimum batch size for TQ is 25 kgs and the minimum number of batches needed is 3 (total amount 75 kgs). The TQ must be produced under cGMP as it is intended for clinical use in humans.

C.4.4 Implement Bioequivalence Study
A Bioequivalence Study is needed to compare product produced by Piramal or another manufacture to the product that was used in previous clinical studies. The study will show there is no meaningful difference between the two tafenoquine products in terms of the drug's safety and the way in which the drug works in the body.

The contractor shall be responsible for executing a study either directly or through subcontractors in full compliance with the relevant regulatory requirements. The protocol shall be formulated to address any and all concerns of regulatory agencies after consultation with the relevant authorities in such agencies. The protocol shall include all relevant study- associate documents such as Case Report Forms (CRFs), Informed Consent (IC), Statistical Analysis Plan (SAP), study-specific SOPs, etc.

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the protocol in full compliance with local regulatory regulations and the applicable GCP/ICH regulatory requirements.

The Contractor shall submit a final Study Report (DELIVERABLE No. 12 /CDRL B006/QASP 8).

C.4.4.a The Contractor shall provide all support services needed to initiate and complete a transporter assay to include but not limited to (p-gp, BCRP, OATP1B1, OATP1B3, OAT1, OAT3, and any others transporter) an appropriate non-clinical test required by regulatory authorities.

The Contractor shall provide support to the Government Product Manager and the TQ IPT in the developing the protocol and related documents (Ex: SOPs, etc.) consistent with and in full compliance with the relevant national and international (GLP) regulatory requirements including current FDA Guidance for Industry, "Drug Interaction Studies -Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations."

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the non-clinical protocol in full compliance with local regulatory regulations and the applicable GLP regulatory requirements.

C.4.5 Implement Clinical Study - Option CLIN 0002 (Est. POP 1 Year)

The contractor shall be responsible for executing a study either directly or through subcontractors in full compliance with the relevant regulatory requirements. The protocol shall be formulated to address any and all concerns of regulatory agencies after consultation with the relevant authorities in such agencies. The protocol shall include all relevant study- associate documents such as Case Report Forms (CRFs), Informed Consent (IC), Statistical Analysis Plan (SAP), study-specific SOPs, etc.

A 30 healthy volunteer subject malaria challenge clinical study will be performed with an anticipated period of performance of three months to nine months. Study drug will be administered as a loading dose, one dose per day for 3 days followed by weekly dosing for 3 weeks. Subjects will be followed with daily smears for 20 days and once weekly through day 60 and as needed for fever post mosquito's exposure. The contractor shall be responsible for all resources at the study sites required for subject screenings and follow-ups. The contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the clinical protocol in full compliance with local regulatory regulations and the applicable GCP/ICH regulatory requirements.

Provide quality assurance services and generate QA reports to ensure timely execution of clinical protocols in full compliance with local regulatory regulations and the applicable GCP/ICH regulatory requirements.

The Contractor shall submit a final Clinical Study Report (DELIVERABLE No. 13/CDRL B005/QASP 9) .

C.4.6 Execute Non-clinical Study - Option CLIN 0003 (Est. POP 9 Months)

C.4.6.a The Contractor shall provide all support services needed to initiate and complete a 28-day toxicology study required by the regulatory authorities.

The Contractor shall provide support to the Product Manager and the TQ IPT in developing the protocol and related documents (Ex: SOPs, etc.) consistent with and in full compliance with the relevant national and international (GLP) regulatory requirements.

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the non-clinical protocol in full compliance with local regulatory regulations and the applicable GLP regulatory requirements.

C.4.6.b The Contractor shall provide all support services needed to initiate an appropriate non-clinical test to evaluate a drug-related N-nitroso metabolite. This metabolite was negative in both a non-GLP and GLP Ames test. The contractor will be provided samples of TQ to be used in the study.

The Contractor shall provide support to the Government Product Manager and the TQ IPT in developing the protocol and related documents (Ex: SOPs, etc.) consistent with and in full compliance with the relevant national and international (GLP) regulatory requirements.

The Contractor shall provide quality assurance services and generate QA reports to ensure timely execution of the non-clinical protocol in full compliance with local regulatory regulations and the applicable GLP regulatory requirements.

The Contractor shall submit a final Non-Clinical Study Report (DELIVERABLE No. 14/CDRL B010/ QASP 10).

C.4.7 Provide Data Management:
On as needed basis, the Contractor shall:

C.4.7.a Provide data management services and/or data management systems, in full compliance with cGCP, ICH/FDA regulations and 21 CFR Part 11. Data management services may include, but are not limited to, Statistical Analysis Plan (SAP) and case report forms development; modification, installation, and/or qualification of data management systems; data capture, data cleansing, queries, and query resolution; database locking and reporting; formulation, as needed, and maintenance of Standard Operating Procedures (SOPs); work instructions and job descriptions related to operation of the data management; creation and operation of individual data entry systems and transfer of data by sites; responding to site queries; and filing CRFs.

C.4.7.b Provide .pdf-formatted files of primary (final) records, CRFs of each participant, study data files on DVDs or HDs and SAS-formatted data files, as needed.

C.4.7.c Perform data entry and CRF filing audits and coordinate coding of Adverse Events (AEs) using MedDRA.

C.4.7.d Provide statistical support services including (but not limited to) the development of SAPs, implement and/or purchase of statistical software, perform statistical analysis, and generate reports in full compliance with the relevant ICH/GCP regulatory requirement for inclusion in regulatory submissions.

C.4.7.e Provide database closure and archiving.

C.5.0 Prepare Project Management Approach
The Contractor shall provide a Project Management Approach. The management approach shall describe the management, processes, integration of the various aspects of the Government SOO and RFP so that the associated risks may be assessed and ability to demonstrate flexible and creative solutions to the management on this effort. Identify significant milestones, decision points, functional oversights and processes that will be used to evaluate program status and progress. Present mechanisms for interactions/communications between the Contractor and the Government. Describe the approach to managing and interfacing with key subcontractors, to include how they will assure subcontractors meet cost, schedule, and performance requirements. The Contractor's Project Management Approach shall describe teaming arrangements including a description of the teaming partner(s) and their core competencies, geographical reach of capabilities, and biographical sketches/CVs of key personnel.

C.5.1 Performance Work Statement (PWS)
The Contractor shall submit a PWS as part of the RFP submission. The PWS will provide the details as to how the contractor intends to accomplish the objectives of the Government SOO and RFP (DELIVERABLE No. 3/QASP 3). The proposed PWS, when accepted by the Government, will be incorporated into and become a material part of the contract at time of award. For that reason, this section shall be a standalone document. Any revisions will require the concurrence of both the Government and Contractor and issued in accordance with a modification to the contract.

C.5.2 Contract Work Breakdown Structure (CWBS)

The Contractor shall submit a CWBS as part of the RFP submission. The Offeror shall submit a CWBS and CWBS Dictionary, using the MIL-STD-881C (http://www.acq.osd.mil/evm/resources/policies-standards.shtml), fulfilling the requirement stated in the Government's SOO (DELIVERABLE No. 4/CDRL B001/QASP 4). The minimum CWBS expected is Level 4; however, the Offeror shall extend CWBS elements as needed to obtain the depth and breadth of detail required to define the contract scope and to accurately describe the proposed effort. The CWBS shall correlate with the PWS and Contract Line Item Numbers (CLINs). This document will be revised by the Contractor, as necessary during the contract period of performance.

C.5.3 Integrated Master Schedule (IMS)
The Contractor shall develop and maintain an Integrated Master Schedule (IMS) (DELIVERABLE No. 5/CDRL B002/QASP 5). The IMS shall contain the planned events and milestones, accomplishments and activities from contract award to the completion of contract. The IMS shall be updated as required by the COR, but not less than annually to show task progress, percent completion, and schedule slippage. Additionally, Contractor shall provide an IMS for all module and sub-section activities outlined in section 4.1a for the NDA Dossier.

C.5.4 Quality Management Plan (QMP)
The Contractor shall develop and maintain a QMP (DELIVERABLE No. 6/CDRL B004/QASP 6). The QMP provides a description of the Contractor's management steps to ensure that all activities of the project are managed in a sound, reasonable way to achieve the Government's objectives and that all deliverables produced are acceptable prior to delivery to the Government. The QMP also describes/assigns the roles and responsibilities of the Government, the Contractor, and any subcontractors.The QMP provides appropriate mechanisms and access for the Government or its designee to audit the Contractor and/or its Subcontractors for regulatory compliance and quality assurance purposes. The Contractor's QMP shall describe in detail the following:

C.5.4.a Quality standards in facilities, equipment, methods, practices, records, controls, and documentation
C.5.4.b Comprehensive GMP, GLP, and GCP compliant systems
C.5.4.c Comprehensive and adequately staffed Quality Assurance Unit
C.5.4.d Established quality agreements with teaming partners
C.5.4.e Approach to technology transfers of processes
C.5.4 f Approach to providing flexibility
C.5.4.g Ability to provide creative and timely responses to the management of the contract and subcontracts.

C.5.5 Kick-off Meeting
The Contractor shall schedule and conduct a kick-off meeting in coordination with the Government within 30 business days after contract award (DELIVERABLE No. 1). The Contractor shall meet with the Government to present an overview of their approach and establish schedules, procedures, and points of contact necessary to conduct the tasks outlined herein. This meeting shall not exceed two hours in length. The Contractor shall be responsible for drafting and finalizing meeting minutes and distributing the finalized minutes to all in attendance.

C.5.6 Recurring Status Meetings
The Contractor shall plan and conduct regular, routine meetings with a quarterly frequency, no later than one (1) week after the end of each contract year quarter,with the Government to review progress and status of activities under this task order (DELIVERABLE No. 2). Each review shall provide insight into expenditures, staffing, progress, risks. The Contractor shall provide project briefings addressing cost/price, schedule, performance, and status of each key element of this task order, noting any problems or risks and alternative and recommended solutions. The Contractor shall be responsible for drafting and finalizing meeting minutes and distributing the finalized minutes to all in attendance.

C.5.7 Quarterly Progress Report (QPR)
The Contractor shall submit a QPR outlining the expenditures, billings, progress, status, and any problems or issues encountered in the performance of this task using format provided by the Government and Contractor (Deliverable No. 7/CDRL B003/QASP 1). The QPR shall include labor hours expended by labor category and CLIN for each task and sub-task. The Contractor shall require all sub-contractors to provide input to the QPR where there are significant tasks related to the prime contract. Significant tasks shall be identified by the Contractor in the initial proposal.

C.6.0 Quality Assurance Surveillance Plan Matrix (QASP Matrix)

ITEM	Indicator	Standard	Acceptable Quality Level	Monitoring Method	Incentive
1. QPR SOO 5.7 CDRL B003 DELIVERABLE 7	Received no later than the 15th of of the month after each contract year quarter	Report of financials, status of tasks, and problems/issues including any subcontractor input	No more than 5 business days late with no less than 95% accuracy for any report in one quarter	100% review	Past performance rating
2. Finished product in final packaging and copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product SOO 4.3.b CDRL B008 DELIVERABLE 8	Contractor shall procure cGMP material NLT 17 months after contract award and provide copies of manufacturing documents, reports, etc., associated with the manufacturing of the bulk drug product	Full compliance with cGMP standards	Full compliance with cGMP standards and delivery NLT 17 months after contract award	100% review	Past performance rating
3. PWS SOO 5.1 DELIVERABLE 3	Received at RFP closing and as required	Shall provide details as to how the contractor will accomplish the objectives of the Government SOO and RFP	Comprehensive, current and accurate throughout contract POP	100% review	Past performance rating
4. CWBS SOO 5.2 CDRL B001 DELIVERABLE 4	Received at RFP closing and within 14 business days of COR request for an update or as required	Contractor shall develop and maintain a CWBS. The CWBS elements shall be extended to define the complete contract scope and shall be to a depth and breadth necessary to accurately describe the proposed effort, to a minimum of Level 4	CWBS defines entire contract scope and extends to at least Level 4	100% review	Past performance rating

5. IMS SOO 5.3 CDRL B002 DELIVERABLE 5	Received at RFP closing and as required, but not less than annually	Contractor shall develop and maintain an IMS by logically networking detailed program activities.	Comprehensive, current and accurate IMS depicting logical network of program activities	100% review	Past performance rating
6. QMP SOO 5.4 CDRL B004 DELIVERABLE 6	Received at RFP closing and as required, but not less than annually	Contractor shall develop a comprehensive QMP to ensure that the project is managed properly and in conformance to all Government requirements. Contractor shall review and update plan as needed, at a minimum annually	Comprehensive QMP that ensures project is managed in a sound, reasonable way to achieve the Government's objectives and that all deliverables produced are acceptable prior to delivery to the Government	100% review	Past performance rating
7. Final CTD & eCTD SOO 4.1.a and 4.1.b CDRL B007 DELIVERABLE 10	Deliver modules 1, 2, 3, 4 & 5 in paper and electronic format within 30 days of government comments	Full compliance with relevant submission requirements	Not more than 5% failure to comply with requirements per module	Progress status meetings	Past performance rating
8. Final Bioequivalence Study Report SOO 4.4 CDRL B006 DELIVERABLE 12	NLT 8 months after Study Initiation	Report ready for submission to the regulatory agency	Minimal revision (less than 3 business day effort) may be required.	100% review	Past Performance rating
9.Final Clinical Study Report SOO 4.5 CDRL B005 DELIVERABLE 13	NLT 1 year after issuance of CLIN 0002	Report ready for submission to the regulatory agency	Minimal revision (less than 3 business day effort) may be required	100% review	Past performance rating
10. Final Non-Clinical Study Report SOO 4.6 CDRL B010 DELIVERABLE 14	NLT 9 months after issuance of CLIN 0003	Report ready for submission to the regulatory agency	Minimal revision (less than 3 business day effort) may be required	100% review	Past performance rating
11. Pre-submission Package SOO 4.1.d CDRL B011 DELIVERABLE 15	NLT the expiration of contract year 3	Package submitted to regulatory agency on planned schedule	Minimal revision (less than 3 business day effort) may be required	100% review	Past Performance rating
12. NDA Submission Package SOO 4.1.e CDRL B012 DELIVERABLE 16	NLT 6 months prior to contract POP expiration	Package submitted to regulatory agency on planned scheduled	Minimal revision (less than 3 business day effort) may be required	100% review	Past Performance rating

C.7.0 Security and Training Requirements
The work under the contract will not require issuance of a computer access card (CAC) or access to the government network.

C.7.1 Contractor Access to USAMMDA Network/DoD Systems:
Not Applicable

C.7.2 Antiterrorism (AT)/Operations Security (OPSEC) Requirements:

AT Level I Training. All Contractor employees, including sub-Contractor employees, requiring access to Army installations, facilities, or controlled access areas shall complete AT Level I awareness training within 15 calendar days after contract start date or effective date of incorporation of this requirement into the contract, whichever applies. The Contractor shall submit certificates of completion for each affected Contractor employee and sub-Contractor employee to the COR (or to the contracting Officer, if a COR is not assigned) within 30 calendar days after completion of training by all employees and sub-Contractor personnel. AT Level I awareness training is available at https://atlevel1.dtic.mil/at.

Access and General Protection/Security Policy and Procedures. The Contractor and all associated sub-Contractors' employees shall comply with applicable installation, facility, and area commander installation and facility access and local security policies and procedures (provided by the government representative). The Contractor shall also provide all information required for background checks to meet installation access requirements to be accomplished by the installation Provost Marshal Office, Director of Emergency Services, or Security Office. The Contractor shall comply with all personal identity verification requirements as directed by DoD, HQDA, and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in Contractor security matters or processes.

C.8.0 CONTRACTOR MANPOWER REPORTING (CMR) - (ACCOUNTING FOR CONTRACT SERVICES) (APR 2011) (USAMRAA)

The Office of the Assistant Secretary of the Army (Manpower & Reserve Affairs) operates and maintains a secure Army data collection site where the contractor will report ALL contractor manpower (including sub-contractor manpower) required for performance of this contract. The contractor is required to completely fill in all the information in the format using the following web address: https://cmra.army mil. **T**he required information includes: (l) Contract Number; (2) Delivery Order Number (If applicable); (3) Task Order Number (If applicable); (4) Requiring Activity Unit Identification Code (UIC); (5) Command; (6) Contractor Contact Information; (7) Federal Service Code (FSC); (8) Direct Labor Hours; (9) Direct Labor Dollars; and, (10) Location. In the event the Contracting Officer's Representative (COR)/Contracting Officer's Technical Representative (COTR) has not entered their data requirements first, the contractor must also enter the COR/COTR required data with the exception of fund cite, obligations, and disbursement data. The **CMRA help desk can be reach at 703-695-5103 or 703-695-5058 for any technical questions. The help desk can also be contacted via email: contractormanpower@hqda.army mil.** As part of its quote or offer, the contractor will also provide the estimated total cost (if any) incurred to comply with this reporting requirement. The reporting period will be the period of performance not to exceed 12 months ending 30 September of each government fiscal year and must be reported by 31 October of each calendar year.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00009	13-Sep-2017	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

X B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: tkelly174740

The purpose of this modification is to incrementally fund CLIN 0001. All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	KELLY GREEN / CONTRACTING OFFICER

15B. CONTRACTOR/OFFEROR	15C. DATE SIGN	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		(b) (6) [redacted] il	09-Sep-2017

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001
The SIC code 8731 has been deleted.

SUBCLIN 000101
The FSC code AN93 has been deleted.
The SIC code 8731 has been deleted.

SUBCLIN 000102
The FSC code AN93 has been deleted.
The SIC code 8731 has been deleted.

CLIN 0002
The SIC code 8731 has been deleted.

SUBCLIN 000203
The FSC code AN93 has been deleted.
The SIC code 8731 has been deleted.

CLIN 0003
The SIC code 8731 has been deleted.

CLIN 0004
The SIC code 8731 has been deleted.

SUBCLIN 000401
The FSC code AN93 has been deleted.
The SIC code 8731 has been deleted.

SUBCLIN 000106 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000106					$0.00

CLIN 0001 Incremental Funding
FFP
Incremental Funding in the amount of $(b) (4) from PR 0011066777
FOB: Destination
PURCHASE REQUEST NUMBER: 0011066777

NET AMT $0.00

ACRN AE $(b) (4)
CIN: GFEBS001106677700001

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000106:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000106:
Funding on SUBCLIN 000106 is initiated as follows:

ACRN: AE

CIN: GFEBS001106677700001

Acctng Data: 021201720182040000066464325 5 R.0001626.13 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 31 JAN 18. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
$(b) (4)	13 SEPT 17
$(b) (4)	1 FEB 18
$(b) (4)	1 FEB 19

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled "Limitation of Funds", FAR 52.232-22.
(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00010	14-Dec-2017	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

X B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

☐ D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: tkelly18900

The purpose of this modification is to:

1. Incrementally fund CLIN 0001 in the amount of $(b) (4) See Summary of Changes for details.
2. All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	PATRICK K HARRIS / CONTRACTING OFFICER TEL: (301) 619-2779 EMAIL: patrickkharris11.civ@mail.mil

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. U	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6)	14-Dec-2017

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000107 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000107					$0.00

CLIN 0001 Incremental Funding
FFP
CLIN 0001
FOB: Destination
PURCHASE REQUEST NUMBER: 0011114630

NET AMT $0.00

ACRN AF $(b) (4)
CIN: GFEBS001111463000001

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000107:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000107:
Funding on SUBCLIN 000107 is initiated as follows:

ACRN: AF

CIN: GFEBS001111463000001

Acctng Data: 021201820192040000665654255 R.0001626.14 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 31 JAN 18. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
$(b) (4)	1 FEB 18
$(b) (4)	1 FEB 19

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled "Limitation of Funds", FAR 52.232-22.
(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
U	1 7

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00011	13-Apr-2018	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC (b) (6) 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: tkelly182256

The purpose of this modification is to incrementally fund CLIN 0001 and make administrative corrections to the contract. All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) SAMANTHA L. CONNORS / CONTRACTING OFFICER TEL: 301-619-6979 EMAIL: samantha.l.connors.civ@mail.mil	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. BY (b) (6)	16C. DATE SIGNED 13-Apr-2018

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000101
The FOB Destination has been deleted.
The PROG code S10 has been deleted.
The WSC Equipment code 000 has been deleted.
The NAICS code 541711 has been deleted.
The MDAP/MAIS Code 000 has been deleted.

SUBCLIN 000102
The FOB Destination has been deleted.
The PROG code S10 has been deleted.
The WSC Equipment code 000 has been deleted.
The NAICS code 541711 has been deleted.
The MDAP/MAIS Code 000 has been deleted.

SUBCLIN 000103
The FOB Destination has been deleted.

SUBCLIN 000104
The FOB Destination has been deleted.

SUBCLIN 000105
The FOB Destination has been deleted.

SUBCLIN 000106
The FOB Destination has been deleted.

SUBCLIN 000107

The FOB Destination has been deleted.
The NAICS code 541690 has been deleted.

SUBCLIN 000201

The FOB Destination has been deleted.

SUBCLIN 000202

The FOB Destination has been deleted.

SUBCLIN 000203

The FOB Destination has been deleted.
The PROG code S10 has been deleted.
The WSC Equipment code 000 has been deleted.
The NAICS code 541711 has been deleted.
The MDAP/MAIS Code 000 has been deleted.

SUBCLIN 000401

The FOB Destination has been deleted.
The PROG code S10 has been deleted.
The WSC Equipment code 000 has been deleted.
The NAICS code 541711 has been deleted.
The MDAP/MAIS Code 000 has been deleted.

SUBCLIN 000108 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000108					$0.00
	CLIN 0001 FFP CLIN 0001 PURCHASE REQUEST NUMBER: 0011160441				
				NET AMT	$0.00
	ACRN AF CIN: GFEBS001116044100001				$(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The Acceptance/Inspection Schedule for SUBCLIN 000101 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000102 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000103 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000104 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000105 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000106 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000107 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000108:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000201 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000202 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000203 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The Acceptance/Inspection Schedule for SUBCLIN 000401 has been changed from:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

To:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000108:
Funding on SUBCLIN 000108 is initiated as follows:

ACRN: AF

CIN: GFEBS001116044100001

Acctng Data: 021201820192040000066565425 5 R.0001626.14 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 31 JAN 19. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
$(b) (4)	1 FEB 19

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled “Limitation of Funds”, FAR 52.232-22.
(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
U	1 3

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00012	07-Sep-2018	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC (b) (6) 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
USAMRAA 5152.232-9000 INCREMENTAL FUNDING

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: tkelly184375

The purpose of this modification is to incrementally fund CLIN 0001. All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
		KELLY GREEN / CONTRACTING OFFICER TEL: 301-619-1346 EMAIL: kelly.r.green.civ@mail.mil
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. (b) (6) BY (
		16C. DATE SIGNED 05-Sep-2018

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000109 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000109					$0.00
	Incremental Funding for CLIN 0001 FFP Incremental funding for CLIN 0001 PURCHASE REQUEST NUMBER: 0011235227				
				NET AMT	$0.00
	ACRN AF CIN: GFEBS001123522700001				$(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000109:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000109:
Funding on SUBCLIN 000109 is initiated as follows:

ACRN: AF

CIN: GFEBS001123522700001

Acctng Data: 021201820192040000066565425 5 R.0001626.14 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 31 JAN 19. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:

Amount	On or about
$(b) (4)	1 FEB 19

b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled “Limitation of Funds”, FAR 52.232-22.
(End Local Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
U	1 3

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00013	28-Dec-2018	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
FAST TRACK DRUGS & BIOLOGICS LLC (b) (6) 5 PARAMUS CT GAITHERSBURG MD 20878-4276		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH-16-C-0002
	X	10B. DATED (SEE ITEM 13) 19-Nov-2015
CODE 4ANW8	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
Unilateral IAW FAR 52.232-22 and USAMRAA 5152.232-9000

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: pmitchel19781

The purpose of this modification is to:

1) Provide final Incremental Funding in the amount of $(b) (4) to CLIN 0001. This CLIN is now fully funded.

See Summary of Changes for details.

All other terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) SAMANTHA L. CONNORS / CONTRACTING OFFICER TEL: 301-619-6979 EMAIL: samantha.l.connors.civ@mail.mil	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. U BY (b) (6)	16C. DATE SIGNED 28-Dec-2018

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000108

The contract type has changed from FFP to CPFF.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000108					$0.00
	CLIN 0001 CPFF CLIN 0001 PURCHASE REQUEST NUMBER: 0011160441				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AF CIN: GFEBS001116044100001				$(b) (4)

SUBCLIN 000110 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000110					$0.00
	Funding for CLIN 0001 CPFF Funding for CLIN 0001 PURCHASE REQUEST NUMBER: 0011284688-0001				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AG CIN: GFEBS001128468800001				$(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000110:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000110:
Funding on SUBCLIN 000110 is initiated as follows:

ACRN: AG

CIN: GFEBS001128468800001

Acctng Data: 021201920202040000066565425 5 R.0001626.16 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A74FG

The following have been modified:

5152.232-9000 INCREMENTAL FUNDING (November 2014)(USAMRAA)
a. It is estimated that the total cost to the Government for the full performance of this contract for the period of 23 NOV 15 to 22 NOV 19 will be $(b) (4) There have been funds allotted for reimbursement of allowable costs, and applicable fee incurred in the performance of this contract in the amount of only $(b) (4) It is estimated that such funded amount shall be sufficient to cover allowable expenses for the period 23 NOV 15 to 22 NOV 19. The amount of the funds currently allotted may be increased by the Contracting Officer without further concurrence of the contractor. It is estimated that the remaining funds will be made available in accordance with the following schedule:
Fully Funded
b. Pending the availability of additional funds, performance by the contractor shall be governed by the contract clause entitled “Limitation of Cost”, FAR 52.232-20.
(End Local Clause)

(End of Summary of Changes)